REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
24 Sept 2013	Final Report	9/30/2008-1/31/2013

4. TITLE AND SUBTITLE

A National Model for Diabetes Prevention and Treatment Program in Civilian and Military Beneficiary Populations (FY07)

5a. CONTRACT NUMBER

FA7014-08-2-0001

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

Air Force Medical Support Agency
Air Force Medical Service Research and Innovations Division
7700 Arlington Blvd.
Falls, Church VA 22042

10. SPONSOR/MONITOR'S ACRONYM(S)

AFMSA, SG5I

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

Distribution Statement : Approved for public release: distribution unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The prevalence of childhood overweight and obesity is increasing at an alarming rate in the United States (US). Prevalence among children and adolescents has doubled in the past 2 decades [1]. There is a strong link between obesity and diabetes, and other significant health problems such as cardiovascular disease and sleep apnea [2, 3]. The probability of childhood obesity persisting into adulthood is estimated to increase from approximately 20% at 4 years of age to approximately 80% by adolescence [4]. It is probable that co-morbidities will persist into adulthood as well [5]. The obesity epidemic is likely to affect the military most immediately as a result of increasing the need for dependent care for overweight and obese children. The purpose of this project was to develop and implement a comprehensive, evidence-based, multi-faceted approach to preventing diabetes in those at risk, as well as improving the lives of those already diagnosed with the disease. The principal investigator focused on transforming currently available knowledge into useful measures for everyday clinical health practice. This project addressed four areas in adult primary prevention for diabetes and cardiovascular disease through the use of web-based tools. The areas included an evidence-based

15. SUBJECT TERMS

Obesity, diabetes, Healthy Behaviors 4 Life (HB4L) ,“Killer Diabetes”, DSME program, Group Lifestyle Balance (GLB)

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Ms. Sandra Bailey
Unclassified	Unclasssified	Unclassified	UU		19b. TELEPHONE NUMBER *(Include area code)* 703-681-6112

UPMC LIFE CHANGING MEDICINE

Final Report

A National Model for Diabetes Prevention and Treatment Program in Civilian and Military Beneficiary Populations(FY07)

University of Pittsburgh Medical Center
Pittsburgh, Pennsylvania 15213

January 29, 2013

Reporting Period: **30 September 2008 – 31 January 2013**

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DISTRIBUTION STATEMENT
Distribution A

UNCLASSIFIED

UPMC LIFE CHANGING MEDICINE

Contract #:	FA7014-08-2-0001
Deliverable #:	5.1.43
Funding Year:	2007
Goal/Initiative:	Focus Area 5
Submitted By:	Paige Carroll
Submission Date:	1/29/13
Description:	Final Report

UPMC LIFE CHANGING MEDICINE

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Objective

The objective of this deliverable is to report on the outcomes, accomplishments, and issues for each project goal. Presented in this report are summaries of each goal inclusive of the final deliverable report number, purpose, hypothesis, a summary of the study design, results, and conclusions. Complete descriptions of all goals can be found in the following final deliverable reports:

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  - Deliverable 1.2.3
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Focus Area 1 - Primary Prevention & Treatment in Children

The prevalence of childhood overweight and obesity is increasing at an alarming rate in the United States (US). Prevalence among children and adolescents has doubled in the past 2 decades [1]. There is a strong link between obesity and diabetes, and other significant health problems such as cardiovascular disease and sleep apnea [2, 3]. The probability of childhood obesity persisting into adulthood is estimated to increase from approximately 20% at 4 years of age to approximately 80% by adolescence [4]. It is probable that co-morbidities will persist into adulthood as well [5]. The obesity epidemic is likely to affect the military most immediately as a result of increasing the need for dependent care for overweight and obese children. Children's Hospital of Pittsburgh of UPMC (CHP), in partnership with the United States Air Force (USAF), has developed a comprehensive evidence-based pediatric weight management program for urban/rural civilian communities and Air Force (AF) populations. The CHP Weight Management and Wellness Center (WMWC) is directed by Silva Arslanian, MD, an expert in the field of pediatric diabetes research, prevention, and treatment.

Evidenced-based clinical protocols were developed and implemented, as well as a group intervention called the Healthy Behaviors for Life (HB4L) based on nationally recognized obesity treatment programs. By involving both the patient and family in these processes and programs, which focus on changing lifestyle behaviors, the hope is to show improvement in or maintaining body mass index (BMI) percentages in pediatric patients. Web-based tools (The Healthy Plate and Big 5 Worksheet) were developed with Carnegie Mellon University (CMU) based on the previous work with community pediatric practices, and are utilized both to educate participants and to track and monitor patient adherence to a patient/provider agreement. By exploring the opportunities to work with community based pediatricians and using web-based tools to track and monitor eating behavior (the aforementioned five healthy lifestyle behaviors) will improve outcomes in a pediatric population. Using web-based tools designed to track and monitor eating behavior and the five healthy lifestyle behaviors as identified by the American Heart Association (AHA) will improve compliance to a healthy lifestyle program in a pediatric population.

Focus Area 1: Goal 1

To examine the effects of 3-month exercise training (aerobic versus resistance exercise) without dieting, on obesity reduction and improving fitness, body composition and risk of Type 2 Diabetes (T2D) and cardiovascular disease (CVD) in overweight and obese adolescents

Deliverable 1.1.4

Purpose

The study employed gold standard methodologies that allowed for exploring potential underlying mechanisms by which different exercise modalities (aerobic versus resistance) influence total and abdominal obesity, liver fat, intramyocellular lipids, and co-morbidities in previously sedentary overweight youth. It is believed that findings of the proposed research will help set clinical guidelines for improving therapeutic strategies in the treatment of childhood obesity and inform public health policy, as it relates to childhood physical activity.

Hypotheses

Hypothesis 1.1: Certain patient characteristics will be associated with and/or predict success or failure in a pediatric clinic-based weight management program.
Hypothesis 1.2: A military pediatric DSME program will improve clinical and behavioral outcomes of pediatric diabetes patients.

Study Design

Overweight (BMI >95th percentile for age and sex) males were eligible for participation in the study. Inclusion criteria required that the subjects be 12-18 years of age in Tanner stages III-V, abdominally obese (age, sex, and race-specific waist circumference >75th percentiles), non-smokers, non-diabetic, and sedentary (no structured physical activity > 2 times per week for past 6 months). Exclusion criteria included syndromatic obesity, use of chronic medications, which influence glucose metabolism, and psychiatric disorders or chronic medical conditions preventing the ability to participate in the study. Subjects who experienced significant weight change (BMI >2-3 kg/m2) during 3 months prior to the beginning of the study were excluded.

Once parents and youth agreed to participation and gave consent, a complete medical history and physical examination was performed by one of the investigators (medical doctors) or certified nurse practitioners.

Prior to initiating the intervention program, all subjects are admitted twice overnight, within a 3 week period (per subject), to the Pediatric Clinical and Translational Research Center (PCTRC) for the completion of the following evaluations: anthropometrics, blood pressure, fasting blood sample, oral glucose tolerance test, hyperinsulinemic-euglycemic clamp, hyperglycemic clamp, cardiorespiratory fitness, muscular strength, dual energy x-ray absorptiometry, intramyocellular lipid content, hepatic triglyceride content, echocardiogram, computed tomography, and B-mode doppler ultrasound of the carotid artery and pulse wave velocity.

After completing pre-intervention evaluations, subjects were randomly assigned in a rolling fashion to one of three intervention groups: (1) aerobic exercise, (2) resistance exercise, and (3) standard care control group (no exercise). Randomization was performed by random number generation by the study coordinator.

Aerobic Exercise Program: Subjects in the aerobic exercise group participated in a 13 week supervised exercise program, three non-consecutive days per week (~60 minutes/session) on treadmill, elliptical, and stationary bike machines.

Resistance Exercise Program: Subjects in the resistance exercise group participated in a 13 week supervised exercise program that included a series of 10 whole body exercises performed on three non-consecutive days per week (~60 minutes/session).

Standard Care Program (aka control group): The standard care control group did not receive any exercise training regimens and were asked to maintain their current activity levels.

After successful completion of the 3-month intervention program, post-intervention evaluations were completed in an identical fashion to the pre-intervention ones. The two overnight PCTRC admissions were completed within 1-3 weeks of the completion of the intervention in all groups. The following evaluations were completed at the PCTRC: anthropometrics, blood pressure, fasting blood sample, oral glucose tolerance test, hyperinsulinemic-euglycemic clamp, hyperglycemic clamp, cardiorespiratory fitness, muscular strength, dual energy x-ray absorptiometry, intramyocellular lipid content, hepatic triglyceride content, echocardiogram, computed tomography, and B-mode doppler ultrasound of the carotid artery and pulse wave velocity.

Results

Since the beginning of the study, 259 individuals were screened by phone, and 89 individuals completed outpatient screening visit at CHP. Of these, 44 met eligibility criteria and consented for participation in this study. After completing pre-intervention evaluations, 42 subjects were randomly assigned in a rolling fashion to one of three intervention groups. Of the 42 boys randomized, 38 completed their assigned treatment [12 aerobic, 16 resistance and 10 control groups].

Subjects in both exercise groups participated in a 13 week exercise intervention, 3 times per week (60 minutes/session) at the downtown Pittsburgh YMCA exercise facility. Subjects in the aerobic training group used treadmills, elliptical machines or stationary bikes at a moderate intensity. Subjects in the resistance training group used stack weight equipment that include a series of 10 whole body exercises (2 sets of 8-12 repetitions per exercise). All exercise sessions were supervised by the study team.

All participants, except one, were admitted twice overnight (*once for the hyperinsulinemic-euglycemic and the other for the hyperglycemic clamp in random order*), within a 3-week period, to the PCTRC before and after the intervention for complete evaluations.

The findings suggest that regardless of exercise modality, regular exercise alone (e.g, without calorie restriction) is beneficial to improve cardiorespiratory fitness and decrease total body fat (%) and abdominal AT (both visceral and subcutaneous AT) in previously sedentary overweight adolescent boys. Furthermore, it was observed that in the absence of changes in body weight, resistance exercise resulted in significant reductions in liver fat content and increases in insulin sensitivity. These findings are encouraging and provide evidence that engaging in regular physical activity alone, 180 minutes/week, is an effective strategy for the treatment of abdominal obesity and insulin resistance without a corresponding reduction in calorie intake in overweight adolescent boys.

Although physical activity is an important factor of the current epidemic increase in childhood obesity, it has been unclear whether regular physical activity alone is associated with reduction in childhood obesity in particular abdominal obesity. This is the first randomized controlled trial which has simultaneously examined the influence of exercise training, either aerobic or resistance, on total and abdominal obesity, liver fat, and intramyocellular lipids, and co-morbidities in overweight youth.

It was found that regular exercise without caloric restriction is associated with improvement in cardiorespiratory fitness and reduction in body fat, including reduction in abdominal fat. This demonstrates the independent benefits of exercise without dietary modification. In addition, even without changes in body weight, resistance exercise significantly improved insulin-related functions, including insulin sensitivity. This demonstrates that exercise in the form of resistance training has metabolic benefits and may reduce risk of obesity-related co-morbidities including risk for T2D and underscores the importance of recommending this form of physical activity to overweight and obese youth.

<u>Conclusions</u>

- Successful completion of the first randomized controlled trial to examine the independent effect of aerobic and resistance exercise intervention on risk factors leading to T2D and insulin resistance in previously sedentary overweight adolescent boys.
- Data analysis indicates that regular exercise, in particular resistance exercise, may be an effective strategy to reduce total and abdominal adiposity, and to improve insulin sensitivity in previously sedentary overweight boys.
- Study findings provide a rationale for further investigating the effects of exercise training on obesity, fitness, and T2D.

Focus Area 1: Goal 2

To complete a 6-month randomized controlled trial using HB4 web-based tools versus standard treatment for patients from community-based practices presenting to the WMWC

Deliverable 1.2.3

Purpose

Patients assigned to the web-based self-monitoring and educational HB4Life program will experience a reduction in BMI percentile (a measure of weight loss) equal to or greater than that of patients assigned to regular, monthly face-to-face WMWC clinical care. In addition, compared rates of completion of participation in HB4Life in the form of dietary and physical activity logs between children in regular and incentive versions (HB4Life+) of the program and rates of completion of the entire study among the three groups.

Hypotheses

Hypothesis 2A: Reduction in BMI percentile among patients assigned to HB4L will be equal or better than reduction in BMI percentile among patients assigned to the standard intervention.

Study Design

Six month randomized controlled trial with randomization according to a stratified block randomization sequence. Study participants were randomly assigned to one of three treatment groups:

Group 1: A routine initial care visit with monthly in-person behavioral and nutritional counseling (standard care group)
Group 2: Routine initial clinical care visit with self-monitoring and education through HB4Life with no in-person monthly follow-up (HB4Life group)
Group 3: Routine initial clinical care visit with self-monitoring and education through a version of HB4Life with a built-in incentive component (HB4Life+ group)

Initial Visits: All children had an identical initial visit which, in addition to a detailed medical evaluation, included comprehensive nutrition and physical activity assessments, and negotiation and setting of goals for behavior change with the child and parent(s).

Control Group: Children in the control group were asked to return to the Center monthly for 6 months. During follow-up visits, a physician or physician's assistant briefly evaluated the child to identify any changes in medical status or concerns. Children and parents then met with a nutritionist who determined whether goals set at the previous visit were met. Reasons for failing to meet goals

were explored, and goals were renegotiated based on the family's input. A comprehensive lesson plan was developed based on successful behavioral weight management programs consisting of 12 "lessons for life." After each child's progress in meeting goals had been discussed, the nutritionist, child, and family together decided upon an appropriate "lesson for life," which the nutritionist then delivered. Ideally, 6 lessons for life were to be completed by the control group over the course of the study.

Internet-Based Group (HB4Life): In collaboration with design specialists, a web-based weight management tool was developed for children called, HB4Life (http://www.hb4life.com). The tool has been available since 2008 and consists of two components: (1) The "Healthy Plate" allows children to monitor their food and beverage intake by searching for, selecting, clicking, and dragging animated food and beverage items with a mouse and adding them to a "virtual" plate. The program also provides a daily graph of fat, sugar, and calories consumed, so that children can observe how their food choices influence overall nutrient intake. (2) "The Big Five Tracker" is a simple tool through which children record their performance related to 5 key habits that influence weight.

Internet-Based Group with Financial Incentive (HB4Life+): Children assigned to this group used a version of HB4Life which was identical to that of the other internet-based group except that it incorporated a financial incentive system based on behavioral-economic principles. The incentive version, known as HB4Life+, included an electronic bank account whose balance rose and fell according to how frequently children completed their daily logs. People are more likely to be motivated by the prospect of losing money they believe is already theirs, than the prospect of earning more by carrying out some behavior.

Results

A total of 180 children were successfully recruited and 60 subjects randomized to each of the three groups. The mean age of all children at the time of enrollment was 11.53 years with a range of 8.02 to 15.99 years and a standard deviation (SD) of 2.09 years. The mean BMI percentile at the time of enrollment was 98.39, with a range of 85.79 to 99.80, and a SD of 1.71%. The sample consisted of 96 girls and 84 boys. There were 146 white children (81.1%) (145 white and one south Asian child), and 34 black children (18.9%). There were no statistically significant differences in mean age, sex breakdown, racial breakdown, or mean BMI percentile at time of enrollment among the 3 groups.

Completion rate for all participants was 37%; 114 children did not return for their 6-month follow-up visit. The completion rates in groups 1, 2, and 3 were 55%, 27%, and 28% respectively. Children in group 1 (standard care) completed an average of 4.67 visits during the 6 month study period.

Study completers included 36 girls (14, 10, and 12 in each of groups 1, 2, and 3 respectively), and 30 boys (19, 6, and 5 in each of groups 1, 2, and 3 respectively). Completers included 50 white children

(26, 10, and 14 in groups 1, 2, and 3 respectively) and 16 black children (7, 6, and 3 in groups 1, 2 and 3 respectively). The racial profile of both enrollees (18.9% black) and study completers (24.2% black) was comparable, and also similar to the racial breakdown of the CHP WMWC's patient population, in general. However, other characteristics of the study completers, such as motivation, which we did not assess, may differ from those who did not complete the study.

The mean change in BMI percentile for the entire sample of completers was a decrease of 0.40%, with a range of a decrease of 5.41% to a gain of 1.48%. The mean change in BMI percentile was -0.35, -0.70, and -0.22 in the control, HB4Life, and HB4Life+ groups, respectively. There were no statistically significant differences in change in BMI percentile among the three groups.

Forty-two of the children who completed the study (62% of completers) had a BMI percentile which either decreased or remained unchanged at their six month follow-up visit (defined as a "success"). There was no statistically significant difference in success rates among the three different groups and no statistically significant difference in the number of successes between boys and girls or between white and black children.

Only 4 children in the HB4Life+ group earned money through the incentive program. These amounts ranged from $10.73 to $88.33 with a mean of $52.17. The remaining children in this group did not complete logs in a timely enough fashion to earn money by the end of the study. The amounts Three of the four children who earned money were "successes."

The primary outcome for this study was change in BMI percentile among intervention subjects compared to control (aka standard care) subjects. It is believed that self-monitoring through the online program HB4Life.com would yield a mean improvement in BMI percentile as good as or better than improvement through face-to-face follow-up. It was found that study completers experienced a reduction in body weight as indicated by a mean decrease in BMI percentile of 0.40%. It was not found that a statistically significant difference in BMI percentile changed among the three groups. These findings support the belief that self-monitoring through HB4Life resulted in a mean improvement in BMI percentile, or weight reduction, equal to that of routine face-to-face follow-up. In addition, parents of participants in the online program reported high levels of satisfaction with HB4Life.

A secondary outcome for this study included the proportion of both control and intervention subjects who attended the 6-month follow-up visit. The completion rates in groups 1, 2, and 3 were 55%, 27%, and 28% respectively. This means that attrition rates in groups 1, 2, and 3 were 45%, 73%, and 72%, respectively, with online program participants being more likely to drop out of the study. The high rates of attrition were disappointing. Such high attrition rates in pediatric weight management studies, however, are not unusual. One Italian study reported an attrition rate of over 90% over a two-year period [6]. A recent review of attrition in pediatric weight management

programs reveals that rates of 55 – 65% are common [7]. A systematic review of web-based weight management programs for children and adolescents, however, revealed much lower attrition rates of 4.9% to 30% [8]. Several papers report African-American race and higher BMI as predictors of attrition from pediatric weight management programs in general [9]. Neither race nor initial BMI percentile were predictive of completion in our study.

Reasons cited often by families for dropping out of weight management studies include dissatisfaction with programs (i.e. "not what is being looked for ") and logistical issues such as distance from home and time required to travel to programs [7]. The study is consistent with these observations as distance from the CHP WMWC was a significant predictor of follow-up. In addition, families reported that they did not schedule or present for appointments because parents were unable to take time off from work, unable to transport their child due to car trouble or their own health issues (e.g., knee issues, having surgery), or children did not want to miss school. Ironically, web-based programs are designed to overcome barriers of distance and lack of time, but were associated with low completion rates in this study.

It was attempted to maintain program adherence and minimize attrition by encouraging families to schedule follow-up appointments at the time they presented for their baseline appointment (and at each subsequent monthly appointment for the standard care group). Families who were unscheduled for appointments received an average of 4 phone calls in attempt to schedule appointments. Families with scheduled appointments also received 2 reminder calls within 1 – 3 days before their scheduled appointment. If a patient did not show or cancelled their appointment without rescheduling, the study team additionally tried to reach them by phone to identify the reason for missing an appointment and to attempt to reschedule another appointment.

It was theorized that an incentive would promote appointment attendance for all groups and utilization of the online program for the HB4Life+ group. The HB4Life+ group logged onto the online program more frequently than that HB4Life group, but neither group logged into the site more than 50 times during the 6 month study period. The use of financial incentives based on behavioral economics did not improve completion rates. This contrasts with the experience of such incentives in adults for weight loss, which have been shown to keep patients successfully engaged [12]. There is limited information about children who dropped out of the study, but can speculate about reasons for the high rate of attrition. The financial incentives for participation (including the $50 for all participants) may be less meaningful to children than to adults. The average child in the study was only 11.53 years old. The value of money may not be well appreciated by younger children in particular.

Most internet-based weight management programs for children and adolescents include a significant component of personal interaction and having substantial personal contact, in-person or remotely, is recommended for internet-based interventions [13]. All children enrolled in the study

were assigned to attend at least two in-person appointments in a 6 month period. In addition, they were encouraged to contact the CHP WMWC's staff whenever they wished with questions or concerns, through clinic visits, email, or telephone. Furthermore, the dietitian-technician did contact enrollees in the online groups to encourage their participation when the frequency of their logging declined. That level of personal contact may not have been enough to prevent significant attrition.

It should be noted, however, that there needs to be a fine balance between providing personal contact and encouraging children to achieve goals through independent use of a web-based program. If too much personal contact is included as part of a web-based program, the practical advantages in terms of cost and time that the Internet provides are eroded. A completely different approach that could have been taken would be to utilize the online programs to supplement the regular clinical program, rather than supplementing the online programs with some personal contact.

It is also possible that the requirement of daily logging for a period of 6 months was too burdensome for many children. Children were encouraged to make logging part of their daily routines (e.g. completing logs just before bedtime). Review of log in data revealed that most participants in groups 2 and 3 were reasonably consistent in their participation in the online program during the initial months of the study and that participation waned over the course of the study period. This might suggest that a loss of motivation during the treatment process occurred and that additional techniques are needed to encourage continued participation over a long period of time are needed to promote program adherence. Since satisfaction questionnaires were not administered to those who dropped out and did not return to the Center, specific reasons for dropping out cannot be determined.

Conclusions

- The mean BMI percentile of children in each group and of all children who completed the study declined modestly, a result consistent with previous weight management studies. Children in each group had similar rates of "success" by either maintaining or decreasing their BMI percentiles.
- The web-based programs were well received by children and families who used them. Though only a small number of children earned financial incentives in the HB4Life+ group, 3 of 4 that did had significant improvements in their BMI percentiles. Web-based programs with financial incentives may be a suitable weight management strategy for a subset of children. Identifying which children can benefit should be a priority for future research.
- Structuring financial incentives based on behavioral economic principles for children in a manner similar to adults may be ineffective, as children may have different ideas of the value of money and loss and reward. The type and structure of incentives for children to achieve healthier weights is also an area worthy of future study.

- Study outcomes suggest that interactive and educational online programs addressing behaviors related to weight status may be an appropriate for motivated families and an alternative, cost effective option to frequent face-to-face clinical care. Future research should explore factors that encourage retention and success in pediatric weight management programs.

Focus Area 1: Goal 3

To develop an effective clinic based lifestyle management program, HB4L, that is both cost effective and reproducible for national adoption

Deliverable 1.3.4

Purpose

The primary purpose of this project was to evaluate the cost effectiveness of the CHP WMWC.

Hypotheses

Hypothesis 3: A program such as HB4L is cost effective and reproducible.

Study Design

In order to estimate patient cycle time and clinical/administrative staff hours for the Weight Management and Wellness Center WMWC, a total of 31 patients were sampled (the Institute of Healthcare improvement suggests a minimum sample size of 15 patients (4)) over the course of 4 months (Sept – Dec 2009).

CHP data analysts developed a cost-benefit analysis for the WMWC based on the following variables:

- WMWC patient volume: Total, new, and return patients based on actual volume for CHP fiscal year 2010.

- Services provided based on actual and typical charge codes: Physicians, behavioral therapists, and dietitians record their services following standard CHP procedures. Physician and behavioral therapist services are recorded into EPIC. Information entered includes service location, department, provider, patient, payer, current procedural terminology (CPT) codes, procedure names/codes, International Statistical Classification of Diseases and Health Related Problems (ICD-9) codes and diagnoses (can be multiple), date of service, related

charges, payments, and payment adjustments. Rates of reimbursement for services vary depending on procedures provided, diagnoses made, and insurance providers and plans.

Dietitian services of medical nutritional therapy (MNT) are recorded into CERNER, CHP's internal billing system. Dietitians record their services with hospital-specific codes according to type of service, length of consultation, and diagnoses.

- Reimbursement rates for services provided: Calculated from a mix of third party payers' typical reimbursement rates. For the purposes of the cost-benefit analysis a conservative estimate of third party reimbursement was provided. To this end, it was estimated that reimbursement rates for physician and behavioral health services utilizing a 40/60 distribution of Blue Cross Blue Shield and the average of two medical assistant programs utilized in Pennsylvania – Gateway Health Plan and Pennsylvania Medical Assistance. (Gateway Health Plan and Pennsylvania Medical Assistance are managed care organizations that provide health care services to members eligible for medical assistance (i.e., Medicaid and Medicare) in Pennsylvania.) Similarly, reimbursement rates for laboratory procedures were estimated utilizing a 40/60 distribution of CHP's fee schedule payment rate for such items and the average of the two medical assistant programs. MNT reimbursement rates are estimated based on payer mix and average provider reimbursement rates for MNT across hospital-wide MNT services.

- Operational expenses: Personnel and non-personnel costs directly associated with operating the WMWC.

Results

This was accomplished first by preparing a cost-benefit analysis utilizing patient time cycle data, evaluating staff clinical and administrative time commitments, and determining operational and staffing expenses, patient volume, clinical services, and potential mixes of third party payer reimbursement rates. Outcomes of the analysis indicate that the costs associated with delivery of the clinic-based weight management program are not balanced by patient volume and third party payer reimbursement for services.

Opportunely, the cost-benefit analysis provides a vantage point for evaluating ways to optimize the potential for generating revenue. Dr. Jodi Krall and Jenny Dee, CHP hospital administrator, visited the duPont Children's Hospital in Delaware in July 2010 and assessed duPont's experience in deploying a pediatric weight management center. The Weight Management Program at A.I. duPont Children's Hospital in Delaware was selected for the following reasons.

1. The program is well-established. The program began in 1988 in response to primary care referrals. It has evolved over the past 20 years, addressing similar issues and challenges that are faced.
2. The program's structure and focus are similar to CHP's. Like CHP's program, duPont's weight management program is based on the Expert Committee recommendations for comprehensive multidisciplinary care. In addition, the duPont program serves a network of primary care providers comparable to the network served by the program at CHP.
3. The program is reported to be financially solvent. This information is based on personal communications between Dr. Silva Arslanian and Dr. Iman Sharif, the Division Chief of General Pediatrics at duPont. This is the first weight management program that project team members have learned of that reports to be funded primarily by third party reimbursement and out of pocket pay.

Information gathered from duPont provided insight into how a program, similar in structure, size and scope, as the CHP program, is able to be financially solvent. It was learned that the duPont program is not responsible for covering the cost of ancillary staff, including dietitians and behavioral therapists, nor do they pay rent or other overhead expenses. In summary, the only cost the duPont program covers is their medical providers' salaries and through billing and collecting, they are able to generate revenue.

The duPont team has not published on their weight management program. However, Dr. Sandra Hassink, Director for Obesity Initiatives, and Dr. George Datto, Clinical Director, participated in the "FOCUS on a Fitter Future" program for the National Association of Children's Hospitals and Related Institutions (NACHRI). As part of their role in FOCUS, they reported to UPMC that they are writing a manuscript describing models for sustainable weight management programs.

Recently (December 2010), NACHRI published, "Planning, Building and Sustaining a Pediatric Obesity Program: A Survival Guide." (Copies of the publication are only available at www.childrenshospitals.net/obesity.) More outcomes will be released in 2011 including a supplement to *Pediatrics.* The document contains relevant information that helps put CHP's program sustainability issues and challenges into context. The following information is based on survey responses from 47 NACHRI member hospitals.

- All programs are concerned about long-term sustainability.
- Most weight management and obesity programs do not make money.
- Nearly all obesity programs described mixed funding streams inclusive of clinical outcome, philanthropy, research grants, and institutional support.
- The most common type of program funding is institutional support.
- Lack of reimbursement for services and high operating costs were the most frequently cited challenges.

- Most programs bill for individual service by the primary medical provider alone. A few programs have successfully established bundled reimbursements.

Thus, CHP's program is not unique with respect to concerns regarding financial solvency and long-term sustainability. It is a national issue shared by all. However, as stressed in the NACHRI document, pediatric weight management and treatment programs must remain sustainable given the chronic nature of childhood obesity and long-term consequences of obesity-related comorbidities and health care costs. To this end, the NACHRI group provides the following recommendations:

- Advocate with federal and state policymakers and third-party payers to encourage payment for obesity-related services.
- Gain institutional support by demonstrating value added in terms of meeting the need of patients and families, meeting the needs of health care providers, preventing future health problems in children, and highlighting benefits to the community.
- Ensure program sustainability by demonstrating program effectiveness, securing continued grant funding, demonstrating financial viability, and sustaining perceived need by the community and institution.

The institutional leadership at CHP has expressed interest in sustaining the weight management program. Findings from the cost-benefit analysis have been reviewed and utilized to explore alternative models that may improve the likelihood of sustaining the clinic, improve patient compliance and program adherence, and, in turn, improve clinical outcomes. A major strength of the study was that all clinical services recorded into the billing and collecting system as if patients were charged for services, which allowed for a more objective evaluation of potential third party payer reimbursement rates. Moreover funding provided by the Department of Defense (DoD) has enabled a program to be build that can be modified rather than starting from scratch to gain institutional support. The DoD funding also enabled demonstration of program effectiveness and establish a presence in the community. In terms of clinical effectiveness, participation in the CHP WMWC program is associated with modest improvement in weight status as evidenced by reduction in BMI percentiles. Given that continual weight gain is the norm in untreated overweight and obese children, reversal of this trend in a clinical setting is encouraging. As for administrative effectiveness, patient/parent satisfaction survey results provided valuable feedback suggesting overall satisfaction with the quality of care they receive at the CHP WMWC.

<u>Conclusions</u>

- The clinic-based lifestyle management program yielded improvements in BMI percentiles. This supports a rationale for determining methods to sustain the weight management program.

- Patient satisfaction was maintained demonstrating patients and parents are satisfied with the quality of care they receive at the CHP WMWC.
- Patient volume and third party payer reimbursement for services did not balance costs associated with delivery of clinic-based weight management program. Very recent findings from other weight management programs suggest that this may be an unattainable goal given current limitations in third party payer reimbursement plans. Future research and programmatic efforts should focus on identifying ways to enable long-term program sustainability while maintaining and improving program effectiveness.

Focus Area 1: Goal 4

The implementation of a clinic based lifestyle management program, HB4L, in a military pediatric population will be an effective program to decrease the percentage of military dependents that are overweight or obese.

Deliverable 1.4.6

Purpose

The purpose was to assess whether the implementation of a clinic based lifestyle management program in a military pediatric population is an effective program at decreasing the percentage of military dependents that are overweight or obese. The following were also assessed: the impact of parental deployment status, race/ethnicity, and geographical and related correlates on program outcomes.

Hypotheses

Military personnel dependents that enroll in the HB4L treatment program will experience a decrease in BMI and BMI percentile over the time-frame of the intervention.

Study Design

The relationship between geographic location and weight status was evaluated via GIS mapping. Study investigators consulted Kristen S. Kurland, Teaching Professor of Architecture, Information Systems and Public Policy, in the H. John Heinz III College and School of Architecture, at CMU. Ms. Kurland conducted a similar GIS mapping study for the CHP WMWC as part of a previous award. Input was also provided by participants in two committees studying childhood obesity: Highmark Childhood Obesity Regional Strategy Committee and the Allegheny County Medical Society's Western Pennsylvania Obesity Task Force. Both committees are located in Pittsburgh, Pennsylvania

and include interdisciplinary teams of physicians, community leaders, architects, city planners, educators, and policymakers evaluating and identifying solutions for childhood obesity.

GIS Factor 1: Analysis of the proximity of a patient's home to the San Antonio Military Pediatric Center (SAMPC) Pediatric Wellness Center at Wilford Hall Medical Center (WHMC) was the first factor of the study. For example, distance from the facility may influence the number of visits made by a participant or may prevent the participant adopting recommendations made by the clinic.

GIS Factor 2: A patient's proximity to built environment features such as parks and fast food establishments was the second factor of the study.

GIS Factor 3: The third factor in the study compared US Census data such as income levels and educational attainment to geographic location in order to show how additional demographic data can be spatially analyzed in comparison to patient locations. Other studies have shown that educational attainment on the part of the mother is correlated with obesity in children [14]. In order to capture important clinical, demographic, physical, family, psychosocial, metabolic and laboratory parameters, the Research Registry was developed. The Research Registry provides a mechanism for tracking clinical outcomes, thereby contributing to the understanding of the etiology of pediatric obesity as well as the effectiveness of obesity intervention and treatment strategies. The Research Registry has been implemented at two sites. It was first implemented CHP to track program data for civilian children and adolescents treated at the CHP WMWC. The Research Registry was also implemented at the SAMPC Pediatric Wellness Center to track program data for military dependents. The CHP WMWC and SAMPC Research Registries are of utmost importance in the follow up of different prevention and intervention strategies of childhood obesity and related health conditions, and in the development of new research directions.

Data for this study were extracted from the SAMPC and CHP WMWC Research Registries. For the SAMPC Pediatric Wellness Center data was available for the 127 patients and for the CHP WMWC Research Registry, patient data was available for 1,526 patients.

Results

Major findings from this study are summarized below:

- Pediatric military dependents participating in the SAMPC Pediatric Wellness Center weight management program experienced an improvement in body weight as indicated by a statistically significant reduction in BMI percentile across time.

- Gender, age, race/ethnicity, and parental deployment status were not associated with improvement in weight status for SAMPC Pediatric Wellness Center patients.
- Number of clinic visits was associated with improvement in weight status for SAMPC Pediatric Wellness Center patients; patients who visited the clinic four or more times were more likely to be successful than patients who visited 2 or 3 times. In addition, as indicated by the GIS mapping results, proximity to the SAMPC Pediatric Wellness Center appears to favor multiple follow-up visits by patients.
- Living close to green spaces or fast food establishments was not associated with changes in weight status for pediatric military dependents participating in the SAMPC weight management program.
- Military and civilian dependents participating in the SAMPC Pediatric Wellness Center and CHP WMWC weight management programs experienced similar improvements in weight status.

A larger BMI percentile improvement in the military patients enrolled in the weight management program was expected compared to those that are not and similar improvements in BMI percentile between military and civilian patients. It was also anticipated those patients enrolled in the weight management program at WHMC and live in a geographic area which has plenty of parks of recreational centers to show greater improvements in BMI percentile than those living further away from such amenities.

As expected, similar improvements were found in BMI percentile between military and civilian patients, and no associations between geographical location and weight status. This was in contrast to findings from a previous GIS mapping study conducted for the CHP WMWC that showed that patients who live closer to parks and farther from fast food have a decrease in BMI z-scores. It was expected, therefore, that ready access to recreational facilities and food of low nutritional value would have an impact on a participant's outcome in the SAMPC Pediatric Wellness Center program. Perhaps military families are less influenced by their geographical location than civilian families.

Study team members were unable to conduct a longitudinal comparison of weight change between SAMPC Pediatric Wellness Center patients and military dependents not participating in the program for reasons explained in Deliverable 1.4.2. However, cross-sectional data obtained from a previous project that was conducted by Lt. Col. Dale Ahrendt provided a historical comparison regarding rates of overweight and obesity in the military dependent population, which is representative of the patients treated in the clinical program.

Lt. Col. Ahrendt conducted a retrospective study to assess the prevalence of pediatric obesity among AF healthcare beneficiaries in the San Antonio catchment area. Data were collected through chart review of 3,406 patients seen in June 2008 at the San Antonio Military Medical Center (SAMMC)

Pediatrics North and South Campus Outpatient Clinics located at WHMC and Brook Army Medical Center (BAMC). Patients were ages 2 to 23 years old with a median age 11.36 years. Of the 3,406 patients, 502 (14.7%) were overweight (BMI % > 85 but less than 95) and 455 (13.4%) were obese (BMI % > 95). The total overweight and obesity rate was 28.1%.

With an AF pediatric healthcare beneficiary population estimated to be 35,000 in the San Antonio catchment area, these figures suggest that approximately 10,000 children and adolescents are eligible for participation in the SAMPC Pediatric Wellness Center weight management program (based on program eligibility criteria of BMI % > 85). Furthermore, the prevalence of overweight and obesity among AF pediatric healthcare beneficiaries in the San Antonio catchment area approximates national statistics. According to National Health and Nutrition Examination Survey (NHANES) data from 2003-2006, 31.9% of children and adolescents aged 2 to 19 years were overweight or obese in the US civilian, non-institutionalized population [15]. These figures underscore the need for the SAMPC Pediatric Wellness Center to deliver weight management services and treat pediatric obesity in the AF pediatric healthcare beneficiary population.

Comparing overweight and obesity statistics between the SAMMC clinics and the SAMPC Pediatric Wellness Center, we note a difference in the ratio of overweight and obese children. For the SAMMC clinics (which are representative of the entire pediatric population), 52.5% of children and adolescents were overweight and 47.5% were obese, when considering just the 28.1% who are overweight and/or obese. Of the patients in the SAMPC Pediatric Wellness Center Research Registry (n=211), 18% were overweight and 82% were obese. The differences in the ratio between the two groups may indicate that SAMMC physicians are more likely to refer patients with a higher BMI percentile (i.e., >95th percentile or obese) to the SAMPC Pediatric Wellness Center for specialized weight management care. It could also mean that patients who are considered obese are more likely to schedule appointments at the SAMPC Center than patients who are overweight.

<u>Conclusions</u>

- The Research Registry provided a useful and standardized mechanism to evaluate weight management program outcomes and compare programs outcomes between military and civilian pediatric populations.
- Pediatric military dependents participating in the SAMPC Pediatric Wellness Center weight management program experienced an improvement in body weight as indicated by a statistically significant reduction in BMI percentile across time.
- 62% of children and adolescents in the sample of military patients participating in the weight management program maintained or improved their weight status.
- The percentage of military patients participating in the weight management program at the 99th BMI percentile decreased from 33.9% at baseline to 29.9% at follow-up. This is important to note given that the 99th percentile is associated with a marked increase in multiple cardiovascular risk factor prevalence [16].

- Number of clinic visits was associated with improvement in weight status for SAMPC Pediatric Wellness Center patients; patients who visited the clinic four or more times were more likely to be successful than patients who visited 2 or 3 times. This highlights the importance of encouraging patients and families to present for routine clinical visits.
- Proximity to the SAMPC Pediatric Wellness Center appeared to favor multiple follow-up visits by patients. Alternative methods to provide continued support to patients who live farther away from the Center should be explored.
- Living close to green spaces or fast food establishments was not associated with changes in weight status for pediatric military dependents participating in the SAMPC weight management program. Military families may be unique compared to civilian families in the way they interact with their environment.
- Military and civilian dependents participating in the SAMPC Pediatric Wellness Center and CHP WMWC weight management programs experienced similar improvements in weight status. This demonstrates that the program may be appropriate for a variety of cultures and settings.

Focus Area 1: Goal 5

A program to support and monitor children with diabetes whose parent(s) are deployed will be implemented at WHMC.

Deliverable 1.5.5

Purpose

Develop a program designed to support children with diabetes whose parent(s) are deployed with the objective of improving the patients' adherence to treatment and glucose control.

Hypotheses

A program designed to support children with diabetes whose parent(s) are deployed will lead to better adherence to treatment and glucose control.

Study Design

Study investigators determined that the deployment program should include the following elements:

- Routine assessment of psychosocial well-being of children and glucose control

- Multidisciplinary (endocrinologist, diabetes educator, and psychologist) support and treatment tailored to individual needs
- Peer-support groups for adolescents with deployed parents
- Education for new caregivers – when a parent is deployed, their spouse or another family member may assume the role of primary or secondary caregiver for a child with diabetes

Identifying a large enough sample of patients at SAMPC who met this criterion (of active duty and deployed parents) within a reasonable timeframe proved to be challenging. The total patient population of diabetic pediatric patients treated at SAMPC is relatively small – reported to be approximately 140 patients – and, of those, many have caregivers who are retired or are not directly involved with the child's diabetes care. An enhanced diabetes self-management education (DSME) program was designed and implemented with an emphasis on supporting patients with deployed parents.

The SAMPC pediatric diabetes education program provides patients with DSME that addresses nutritional management, physical activity, monitoring, medication, preventing, detecting and treating acute complications, goal-setting and problem-solving, psychological adjustment, and treating chronic complications through risk reduction. The SAMPC DSME program is an American Diabetes Association (ADA) recognized program indicating that it includes quality DSME services that meet the ADA National Standards. In addition, as a recognized DSME program, it meets criteria for Medicare and other third-party payer reimbursement.

The enhanced DSME program includes the following elements and implementation methods:

1. Routine Assessment of Psychosocial Well-Being of Diabetic Children and Glucose Control

Diabetes management consists of an integrated approach involving routine assessment and proactive management of high-risk patients. Given research findings that children with deployed parents are at increased risk for psychosocial issues, the patient's health related quality of life (HRQOL) is evaluated during patient encounters. HRQOL measurement at the point of care helps facilitate communication between patients/caregivers and health care professionals by providing systematic assessment of patient and caregiver perception of the child's current functioning. The HRQOL is measured with the Pediatric Quality of Life Inventory (PedsQL) and the PedsQL 3.0 Type 1 Diabetes Module.

2. Multidisciplinary Support and Treatment Tailored to Individual Needs

PedsQL scores are used to tailor DSME recommendations to the specific needs of the child and family. Using the PedsQL diabetes-specific module, the diabetes care team can quickly gain an appreciation of the family's current difficulties and target educational, behavioral and/or medical

recommendations appropriately [17,18]. Pediatric endocrinologists, certified diabetes educators (CDE), and psychologists work together to determine the best approaches to support and care for patient-specific needs.

3. Peer Support Groups for Adolescents with Deployed Parents

A peer support group was developed for diabetic patients ages 13-18. Under the direction of a diabetes educator and psychologist, the group provides a safe environment for adolescent patients to share feelings and concerns that relate to their condition and experiences with a deployed parent or other family or social circumstances. Peer interaction creates a sense of inclusion, helping adolescent patients realize that they are not alone and that there are other individuals similar to them who also must deal with diabetes self-care. The psychologist is available to lead the group in discussing feelings about diabetes and the diabetes educator will provide direct conversation and/or answer questions about diabetes management.

4. Education for Caregivers

When a parent deploys, their spouse or another family member may take on the role of primary or secondary caregiver for a child with diabetes. Newly assigned caregivers must be educated to care for children with diabetes. Proper diabetes education for a family member(s) of a child with diabetes is intense and complex and requires an educator with a set of skills including: in-depth knowledge of pediatric diabetes, proper communication skills, and ability to tailor education to specific child and family needs [19].

Results

The purpose of this project was to develop a program designed to support children with diabetes whose parent(s) are deployed with the objective of improving the patients' adherence to treatment and glucose control. A support program was developed, inclusive of peer support groups and educational sessions for new caregivers of diabetic children and incorporated these elements into the evidenced-based pediatric diabetes education program. Led by a multidisciplinary team of pediatric CDE, endocrinologists, and psychologist, the program is designed to identify physical and psychosocial barriers to diabetes self-management care and tailor interventions to each child and family's circumstances, with an emphasis on supporting patients with deployed parents.

A total of 128 patients participated in the program during the award period. Prior to the commencement of the award, SAMPC providers reported the total patient population to be roughly 140 children and adolescents. If this value is accurate, then most pediatric diabetic patients served by SAMPC participated in the diabetes education program and suggests that the study findings are generalizable to the patient population as a whole.

The primary outcome for this project was successful improvement in blood glucose control, which was defined by a reduction in hemoglobin A1C values equal to or greater than 0.5% as indicated in the metrics table below. For the relevant patients (≥ 6 years of age) who participated in the diabetes education program on at least two occasions, a statistically significant reduction was observed in mean hemoglobin A1C values (Δ = 0.60%) between baseline and most recent follow-up clinical visit, which demonstrates improvement in glycemic control. On an individual basis, 47.4% patients decreased their hemoglobin A1C values and 38.5% decreased their hemoglobin A1C values by at least 0.5%.

Participation in the diabetes education program also resulted in a 10.7% increase in the percentage of patients who met ADA-set optimal hemoglobin A1C levels. Achievement of optimal glycemic control has both immediate and long-term health advantages. The ADA acknowledges that attainment of optimal hemoglobin A1C goal values is challenging and may not be achievable for all children and adolescents, particularly for children with frequent hypoglycemia or hypoglycemia unawareness. Furthermore, literature indicates that children and adolescents with diabetes consistently demonstrate suboptimal glycemic control [17-19]. These facts underscore the program's effectiveness in supporting pediatric patients' blood glucose management.

No statistically significant differences in HRQOL indicators or glycemic management in terms of parental military status were found. It was expected that patients with deployed parents may present with increased psychosocial issues, but HRQOL as measured by the PedsQL scores did not reflect this hypothesis. However, relatively few patients had parents who were deployed, which limited the meaningfulness of the analysis. Longer term assessment of more patients with deployed parents may unveil additional findings that we were unable to assess in this study.

It was anticipated that, as a whole, military health care beneficiaries with diabetes may experience a higher rate and extent of psychosocial issues as compared to children treated in a civilian outpatient setting. Interestingly, the HRQOL mean scores were comparable to those of larger samples of pediatric patients from the general population. Regardless, assessing health related quality of life with all pediatric diabetes patients did allow the level and extent of psychosocial issues on the health of military dependents with diabetes to be evaluated and to tailor advice accordingly.

Conclusions

Strengths

- A program was developed to support diabetic children with deployed parents, which includes routine assessment of psychosocial well-being and glucose control; multidisciplinary

support and treatment tailored to individual needs; peer-support groups for adolescents; and education for new caregivers.

- The SAMPC diabetes education program was associated with improvements in glycemic control as evidenced by lowering hemoglobin A1C values.
- It was recognized early on that the program may have limited impact given the number of children with deployed parents and if the program was to be administered outside of the existing DSME program. A proactive approach was taken to address these limitations.
- It was also recognized that all pediatric patients may benefit from elements of the deployment program and that adding these elements to the existing DSME program may improve DSME care for all patients.
- Implementing and evaluating an enhanced DSME program will provide meaningful information to medical providers and military leadership regarding care for pediatric patients with diabetes. In addition, findings will support enhancements or refinement of the program to better serve the needs of the patient population.
- The enhanced DSME program is designed to be tailored to individual patient needs.
- Patients, parents, and providers all provided positive feedback regarding their responses to the diabetes education program.
- SAMPC pediatric diabetes education program, inclusive of deployment program elements, serves as a potential model for other military treatment facilities.
- Based on information gathered during patient encounters during this study period, further research into causes of and methods for addressing psychosocial issues that impact pediatric diabetic patients of military families may be warranted.

Weaknesses

- Standard clinical flow and patient encounters were utilized to administer the program and evaluate data collected from these visits to evaluate the program outcomes. This "study design" (compared to the gold standard of a randomized control trial) presents limitations regarding the robustness and generalizability of the result. However, it is the most feasible and realistic study design at this time and does provide a "real life" setting.
- Patients are somewhat inconsistent (fail to schedule follow-up visits, no-show or cancellation appointments) in presenting for their patient visits. Unfortunately, this is a typical occurrence for many outpatient programs designed to improve health-related behaviors. Similar inconsistencies exist in the DSME program at CHP as well as in the adult Diabetes Center of Excellence outpatient clinic located at WHMC. Even with established procedures for scheduling patient visits and emphasis on importance of presenting for follow-up care, patients and parents may not adhere to recommendations. Notably, the diabetes education program is less than two years old and it takes time to establish relationships and rapport with patients and families and secure their confidence and buy-in the value of program participation. Since the inception of the program, project team members have worked closely with providers to establish regular multidisciplinary clinics and encourage providers to

set their template schedules at least three months in advance. Implementation of these changes will enable patients and parents to schedule future appointments during a clinic visit.

- Competing demands during patient visits may limit the scope of services and assessments that can be completed during a patient encounter. Time limitations, both for providers and patients/parents, as well as other issues such as priority of addressing most urgent care needs (e.g., recent diabetic ketoacidosis event, patient suicidal tendencies, etc) may mean that the patient does not have an opportunity to complete a HRQOL questionnaire or satisfaction survey or may not have hemoglobin A1C levels assessed.

Focus Area 2 - Primary Prevention of Diabetes and Cardiovascular Disease in at Risk Adults

There is extensive evidence that both type T2D and CVD can be delayed or even prevented through programs that focus on empowering participants in the areas of food choices and physical activity [20, 21]. People are empowered when they have sufficient knowledge to make rational decisions, sufficient control and resources to implement their decisions, and sufficient experience to evaluate the effectiveness of those choices. There is now a national movement toward patient-centered, empowerment approaches in facilitating necessary lifestyle behavior changes in chronic disease prevention and treatment. In its previous work, UPMC has successfully implemented and evaluated empowerment-based diabetes and CVD risk reduction programs in underserved communities and in primary care settings. Investigators at UPMC modified the Diabetes Prevention Program (mDPP), trained preventionists and deployed prevention efforts in a variety of settings using urban/rural providers to implement multiple methodologies. A centralized Diabetes Prevention Support Center (DPSC) and a Physical Activity Resource Center (PARC) were established to support these efforts, as well as to provide wide spread training and assistance with prevention services.

Focus Area 2 - Goal 1a

The overall objective of this non-blinded, cluster designed, randomized controlled trial (REACT Randomized Control Trial (RCT)) is to address health care needs of individuals living in rural, underserved communities through implementation of a model of T2D and CVD reduction focused on participant empowerment in the areas of food choices and physical activity

Deliverable 2.1.5

Purpose

The study aimed to determine 1) if three different Group Lifestyle Balance (GLB) intervention modalities are effective in decreasing risk for diabetes and CVD and 2) examine and understand if subjects, from a group that was given the option to choose the GLB intervention modality, will experience greater improvement in outcomes and sustain the improvement longer compared to subjects in groups in which the modality was predetermined.

Hypotheses

Hypothesis 1A: At least 50% of subjects in each intervention group will achieve weight loss of at least 5% of their body weight and/or decrease at least one component of the Metabolic Syndrome (MetS).

Hypothesis 1B: Subjects who lose at least 5% of their body weight and/or decrease at least one component of the MetS will sustain these improvements in the long term (6 month follow/up) in each intervention group.
Hypothesis 1C: Subjects in the Self Selection of Modalities group will be more likely to achieve at least a 5% weight loss and/or decrease at least one component of the MetS following the intervention and in the long-term (6 month follow/up) than subjects in the other three groups.
Hypothesis 1D: Subjects in the Self Selection of Modalities group will have greater reductions in fat and calorie consumption and larger increases in physical activity following the intervention and in the long-term (6 month follow/up) than subjects in the other three groups.

Study Design

This study was a non-randomized, prospective, intervention study that utilized a four group design. The study took place in eight rural, underserved communities in southwestern Pennsylvania between October 2009 and December 2010. The eight study communities are socioeconomically depressed areas with high prevalence rates of chronic disease. The study was carried out in three phases: phase 1: training and certification in standardized measurement techniques; phase 2: community-based screening to determine the prevalence of abdominal obesity and being overweight in the study communities and to recruit eligible individuals to take part in the intervention; and phase 3: provision of the intervention with 3 and 6 month follow-up including clinical assessment.

Phase 1: Training and Certification: Phase I consisted of the preventionist and lay health coach training. All preventionists attended a 2 day GLB training workshop delivered by DPSC. The University of Pittsburgh Diabetes Institute (UPDI) research staff conducted additional trainings specific to the study and its protocol and procedures. Study Arm Coordinators were implemented to work closely with the preventionists and lay health coaches at each community site, to ensure that study functions were carried out properly. The entire Rethinking Eating and Activity Study (REACT) research team received clinical measures training and certification in the measurement of blood pressure, waist circumference, weight and height by the University of Pittsburgh DPSC staff or their designees.

Phase II: Community-Based Screening: Multiple community-based screenings were conducted in each of the eight study communities. Subjects were screened for the presence of an increased waist circumference (> 40 inches in men and 35 inches in women) and elevated BMI (≥ 25 kg/m2). Evidence demonstrates that these two parameters serve as a proxy for diabetes risk and offer a practical, inexpensive alternative to traditional community-based screenings [22-25]. Eligible subjects were invited to take part in Phase III of the study. Those who were determined ineligible were referred to other exercise and healthy lifestyle programs in their communities.

Phase III: Group Lifestyle Balance Interventions:
Face to Face: The intervention for this arm of the study consisted of 12 group education sessions that took place over the course of 12 - 14 weeks. Subjects met as a group for up to 90 minutes/session. The intervention focuses on healthy food choices, fat and calorie intake, and physical activity. One trained preventionist, per community, delivered the intervention. One lay health coach, per community, communicated with subjects and identified barriers and solutions to promote program engagement and retention. In addition, the lay health coaches aided in the logistics of the study and shared relevant experiences to initiate class discussion.

DVD: This intervention utilized a DVD series that is based on the GLB program. The DVD covers all of the sessions of the 12 week GLB program and focuses on healthy food choices, fat and calorie intake, and physical activity. Sessions are portrayed by professional actors playing both the preventionist and the subjects. The subject completed the program at a comfortable pace over a 12-14 week period. REACT staff members recommended that subjects watch one session per week, perhaps setting aside a specific day and time each week to view each session. Subjects completed all activities as if they were attending a group session, including keeping track of what they ate and their physical activity levels. Staff called participants weekly to offer information, support, and reminders, as needed.

Internet: The intervention for this study group consisted of the utilization of the DVDs as described above but accessed via the internet. In addition to viewing the DVDs on line, the intervention incorporated behavioral tools such as email prompts for online self-monitoring of eating patterns, physical activity and weight, and a graphing capability to visualize progress made towards stated goals. Subjects were supported via electronic counseling. If staff found that a subject did not log on to the REACT website for over a week and did not respond to an email inquiry, a phone call was made.

Self Selection: Subjects in the communities randomized to this arm of the study were able to self-select their intervention modality from the aforementioned interventions. Subjects were limited to one modality to avoid contamination and bias in the results.

Four hundred and thirty-nine of 493 eligible subjects enrolled in the intervention (Face to face: n=121, DVD: n=113, Internet: n=103, Self Selection: n=102). Each subject received a copy of the GLB handouts, a fat and calorie counter, self-monitoring books for keeping track of food and physical activity, a pedometer, measuring cups and spoons, and a digital bathroom scale. All subjects were asked to self-monitor food intake and physical activity throughout the 12 week intervention and were given feedback concerning progress.

Results

The prospective intervention study demonstrated that greater than 50% of participants in all GLB intervention groups lost at least 5% of their total body weight following the intervention. Of the participants who achieved this weight loss goal, 85-100% of them sustained the weight reduction at the 6 month follow-up time. The same pattern was apparent for 7% weight loss as well. Participants who achieved these goal levels weighed, on average, 20 pounds less at follow-up than they did at baseline. Additionally, as hypothesized, the self-selection group had the largest proportion of individuals achieve the 5% weight loss compared to other groups.

All GLB groups experienced significant reductions in the proportion of participants with components of the metabolic syndrome following the intervention. The prevalence of abdominal obesity decreased significantly in all groups at 3 month follow-up and the improvement was sustained at 6 month follow-up. Although most components of the metabolic syndrome were improved at three month follow-up, abnormal HDLc levels did not. It often times takes longer to observe an effect of physical activity on HDLc than other cholesterol parameters. The proportion of individuals with abnormal HDLc levels decreased at the 6 month follow-up time in all groups except for Internet. After adjusting for necessary covariates, significant within group differences in the components of the metabolic syndrome remained but between group differences in outcomes were not apparent. When the data were examined at 6 month follow-up, there was no increase in the proportion of individuals with any component of the metabolic syndrome, and therefore, improvements were sustained. Indeed, hypertension status and abnormal HDL levels continued to improve over time.

Behavioral and psychosocial outcomes improved in all GLB groups as well. The number of minutes of physical activity increased in all groups and by week 5 of the intervention, and participants met the 150 minutes of physical activity goal. Additionally, across all participants and groups, the proportion of participants who ate fewer calories in order to lose weight increased significantly as did the proportion that ate less fat. Participants' quality of life increased significantly throughout the course of their participation in the REACT study.

In conducting community interventions, there are various limitations that may affect the study results. For example, in the study, all subjects were volunteers. This inherently introduced volunteer bias, as the subjects who participated were most likely more interested in losing weight than the general population. Additionally, as is typical with most community studies, males were under-represented with 13.9% participation. Although the recruitment of subjects was extremely successful, the number of subjects who decided to attend a 3 month reassessment was lower than expected. It was still powered to detect significant differences in the primary and secondary outcomes. Therefore, it is not possible that the reported findings are subject to Type II error, and the findings that showed statistically significant differences represent true differences. As attrition may be perceived as a major limitation in the data, all of the multivariate models were mixed models, which are able to account for attrition.

Conclusions

Adults in rural, underserved communities are at increased risk for diabetes and/or CVD based on their BMI and waist circumference alone. The rural, underserved community is often a difficult population to use in research studies. Often times, their socioeconomic and geographic disparities prohibit them from taking part in programs and studies to help to improve their health. To reach and target the largest number of individuals in this community and to have a large scale impact on diabetes and CVD risk, the REACT study screened individuals at risk for diabetes and CVD based on their BMI and waist circumference. This screening technique was low cost, extremely efficient, and provided a high yield of at-risk individuals for the GLB interventions.

In addition to the scalable, low cost screening, REACT instituted a sound, collaborative research infrastructure within the study communities. Researchers from UPMC and the University of Pittsburgh collaborated with community hospitals and partners to implement all of GLB interventions throughout southwestern Pennsylvania. The staff members at the community sites were responsible for all of the community logistics, such as participant recruitment, appointment scheduling, teaching the GLB, etc, while the research staff were responsible for collecting all research data and instituting intervention fidelity measures to ensure that unanticipated problems or events did not occur.

Health professionals, payers, and policy makers, worldwide, increasingly recognize the need for cost-effective, scalable community-based primary prevention efforts. The REACT study provided the first opportunity to compare the effectiveness of several GLB interventions in multiple underserved, rural communities. To meaningfully impact public health policy and clinical care, understanding the comparative effectiveness of each primary prevention modality in multiple community settings is critical. Efforts to make primary prevention a billable and reimbursable service are ongoing at the local and national levels.

Deliverable 2.1.8

Purpose

A cost effectiveness analysis (CEA) of a non-blinded, cluster designed trial (REACT RCT) which was designed to test the effectiveness of implementing a GLB intervention in eight rural underserved communities.

Hypotheses

Hypothesis 1E: Within group cost effectiveness will be greater in all groups compared to national diabetes prevention data

Hypothesis 1F: Allowing participants to self-select their intervention modality will be more cost effective than the predetermined prevention methodology.

Study Design

Costs for each intervention group will be measured using direct medical costs, direct non-medical costs, and indirect costs associated with the intervention over 6 months. The outcome of the CEA is the cost per Quality Adjusted Life Year (QALY). Incremental cost estimates from the health system and societal perspectives were applied to the number of people who would need to be treated with a specific intervention in order to prevent one case of diabetes.

A four-state Markov decision model was developed to estimate costs, progression of diabetes, and quality of life, which directly incorporated intervention costs, effectiveness, and adherence rates for follow-up measures from the REACT study . The REACT study and published literature were used as the data sources for these analyses. The target population included REACT participants with a body mass index ≥25 kg/m^2 and who were abdominally obese (waist circumference >40 inches in men and >35 inches in women).

Results

Compared to the DVD modality, the Face-to-Face modality is a sound investment, while, in comparison with the no intervention modality, the Face-to-Face modality appears to be an economically reasonable investment. If larger decreases in diabetes risk were observed or if there were greater intervention effects on weight loss (i.e. participants would have lost more weight), there may be a potential for the Face-to-Face, DVD, and Self-Selection modalities, compared to the no intervention strategy, to be cost-effective.

Conclusions

Strengths

Results in this analysis represented a large, underserved, and rural community-based population at risk for diabetes. Therefore, the results are likely to be generalizable to other populations or health care settings. Additionally, REACT investigators were able to collect and provide study data to the cost team, rather than having to rely heavily on the published literature to build the cost models.

The REACT study provided the first opportunity to compare and contrast the cost effectiveness of several GLB interventions to each other and to a no- intervention modality. These types of analyses

could be used to inform policy and decision makers about sound investments in primary prevention efforts.

Limitations
The cost effectiveness analysis had two caveats that deserve mention. First, the model used several conservative practices and assumptions. Therefore, interpretations of results are contingent on data quality and model assumptions, including participant adherence.

Additionally, in a cost-effectiveness analysis, there is a need to inflate all monetary costs to a common base year for performing calculations and comparisons. In the analysis, costs in 2000 US dollars, not 2010 US dollars, were used since the US Consumer Price Index of 2010 used to convert the monetary costs was not complete at the time of analysis and reporting. Choice of the base year for costs is based on scientific judgment and what other comparable costs are available in the literature. Also, 2000 US dollar costs were applied in all published literature that was used in the analysis. Using costs in 2000 US dollars were not be expected to greatly underestimate the costs of the intervention strategies "relative to" the costs of the no intervention strategy in any particular year. That is to say, the "incremental cost" (i.e., difference in costs) between the intervention modality and the no intervention modality would not be greatly influenced. Moreover, the choice of base year for the costs would not be expected to influence the criteria for cost-effectiveness (i.e., $100,000-$300,000 per QALY) because the ratio of cost relative to effectiveness remained the same.

Focus Area 2, Goal 1b

To conduct a RCT at Hershey Medical Center to evaluate a Virtual Lifestyle Management (VLM) Intervention

Deliverable 2.1.14

Purpose
The Pittsburgh-Hershey Internet Translation (PHIT) Study was designed to test the short-term effectiveness of an online adaptation of the Diabetes Prevention Program's (DPP) lifestyle intervention, delivered in coordination of primary care medicine. The RCT comprises two study arms: (1) VLM and (2) Self-Access to Online Information (SAOI).

This PHIT study compared the effectiveness of two online strategies for delivering the DPP lifestyle intervention in coordination with primary care medicine. One of these approaches, termed VLM, provided online delivery of the comprehensive DPP lifestyle intervention, including the DPP lifestyle curriculum, online support from a lifestyle coach, technical tools for self-monitoring diet and physical

activity, and links to reputable online resources. The other, termed SAOI, provided guided access to the publicly available DPP lifestyle intervention materials, along with a single counseling session of how to use these materials. Following the recommendations of practical clinical trials, the arms were chosen for their policy relevance; [26] VLM represented a comprehensive online lifestyle approach fulfilling the recommendations of the US Preventive Services Task Force and SAOI represented a minimal online approach to providing access to the DPP lifestyle curriculum, goals, and tools for lifestyle support.

Hypotheses

Clinic patients who are enrolled in a VLM intervention will report greater reductions in weight loss, fat and caloric consumption, and larger increases in physical activity, over the period of the intervention than the patients in a SAOI group.

Study Design

Separate orientation sessions were held for the two study arms. In each arm, the participants were educated about the DPP lifestyle intervention and its health effects. Each participant was given a pedometer and a book of fat/calorie values for common foods, and they were taught how to use these self-monitoring tools. In addition, study procedures were reviewed.

Participants in the SAOI group were then given printed information about how to access the public-access DPP online materials and how to download the lifestyle curriculum's participant handouts (http://www.bsc.gwu.edu/dpp/lifestyle/dpp_part.html). They were encouraged to complete the 16 core DPP lessons regularly over the next 4-6 months, along with self-monitoring of their fat, calorie, physical activity and weight. This was the extent of their intervention.

At the orientation session, those patients randomized to the VLM intervention were provided with instructions for logging into the comprehensive online lifestyle program and completed an online lesson instructing them on how to use the software during the orientation session. They were encouraged to complete the 16 core DPP lessons on an approximately weekly basis, and then to work their way through additional monthly lessons that had been derived from supplemental DPP materials. Details of the comprehensive online DPP lifestyle intervention have been previously published [27]. It includes interactive online versions of the DPP lifestyle interventions, personalized online lifestyle coaching, technologic tools to facilitate self-monitoring of weight, diet and physical activity, and links to relevant online resources. The program generated automated reports for the referring physicians on a quarterly basis to encourage dialogue about healthy lifestyles during routine primary care visits.

For all participants, any significant new health issues that are communicated to study staff were shared with the referring physicians in an effort to better integrate lifestyle management with health care delivery.

Several measures of body size were collected including height and weight, which were measured with a calibrated digital scale and stadiometer and used to calculate BMI. Waist circumference was measured at the level of the umbilicus. Blood pressure was measured with an Omron digital blood pressure monitor. The Diet Habit Survey was administered to estimate the amount of fat ingested as a percentage of total calories [28]. Physical activity was assessed using validated survey items from the Behavioral Risk Factor Surveillance Survey. Patient satisfaction data were collected using a survey item adapted from the TSUQ [29].

Primary care patients were recruited from primary care clinics at a large rural academic medical center. A total of 124 participants were enrolled between April 8, 2010 and July 29, 2010, 61 to the VLM arm and 63 to the SAOI arm. Recruitment was extended beyond the original plan of 100 participants because a higher percentage of participants never logged into the VLM program than had been anticipated from the pilot study.

Results

In the short-term weight loss study, it was demonstrated that both comprehensive and minimal online approaches to providing the DPP behavioral curriculum to obese primary care patients can result in over three kg of weight loss. Point estimates for weight loss, dietary improvements and patient satisfaction were higher in the VLM group than the SAOI group, though the differences were not statistically significant. Minimal change in physical activity was seen in both groups. While no effect was found on average blood pressure values, the exclusion of people with uncontrolled hypertension necessitates that most participants' blood pressure was well-controlled at baseline and thus it was expected to see little change in average blood pressure values. It is also possible that individuals were able to reduce their antihypertensive needs without seeing a change in measured blood pressure.

Sub-group analyses showed that men lost more weight than women, but that older ($\geq$60) age and literacy were not associated with weight loss in this sample. Engagement with the VLM program (with use beyond 30 days) was clearly associated with more weight loss, while advanced computer skills showed a trend towards less weight loss success. It is possible that the computer skill finding may reflect individuals with more computer skills having lower tolerance for the many technical problems that arose during the intervention. While a sizable proportion of participants found the interventions to be satisfactory, VLM satisfaction levels were lower than had been found in the pilot study, which may reflect a different participant experience with the program (e.g., the considerable

software malfunctions that were experienced in PHIT), or a difference in the study samples' acceptance or comfort level with online intervention.

Conclusion

Strengths

- Primary care physicians and patients showed considerable interest in having access to online lifestyle management options, with 214 referrals from three clinical sites in under 5 months.
- Many VLM participants have demonstrated sustained use of the comprehensive online intervention and, on average, participants who logged in after one month lost 5.5 kg.
- Both groups lost >3 kg of body weight over 4-6 months of follow-up and decreased fat intake. The SAOI group also led to increased median levels of physical activity.
- The sample reflects a wide range of weight-related health problems, promoting generalizability of the findings.
- The rural setting is one in which lifestyle resources are particularly lacking and long distances between individuals' home and their clinical sites makes the provision of clinically-linked counseling particularly difficult; the Internet may help overcome these barriers.
- After lagging behind other settings for years, Internet access has recently increased particularly rapidly in rural regions.
- In this "practical trial" design, in which all interventions were policy relevant and active, both groups lost weight. While the VLM group lost more weight, the study was underpowered to detect a 1.3 kg difference in weight loss between the two groups.
- Short-term loss in weight is often transient so may not result in long-term improvement in weight-related health risk. This may have been particularly true for individuals in the SAOI arm as a number of non-intensive lifestyle interventions have promoted transient weight loss in the primary care setting, but clinically significant ($\geq$3 kg) weight loss is typically not sustained to one year, the time-frame that is generally accepted as reflecting a clinically meaningful lifestyle intervention. More intensive interventions, such as VLM, are typically more likely to promote longer-term weight loss. Thus the short-term PHIT data may or may not have reflected clinically meaningful results (1-year weight change).
- Multiple technical problems created barriers to the intended ease of use for the VLM approach. The research team worked closely with the vendor to make sure that these issues have had minimal impact on the participants' experience but a number of individuals expressed frustration with the technical difficulties. It was likely that this frustration was

reflected in the study's participant satisfaction data and possible that it was reflected in the under performance of the VLM intervention compared with the prior Pittsburgh pilot site.

- While rates of Internet access have recently increased in rural US settings, Internet skills or comfort level may lag behind access, reducing the generalizability of these findings to other settings.

Focus Area 2: Goal 2

Develop a targeted marketing campaign for prevention with national partners and evaluate it in the PRIDE communities.

Deliverable 2.2.8

Purpose

The purpose was to develop a systematic evaluative approach for creating messages regarding health improvement. These messages were to be deployed in both rural/small town and urban markets. It was to be determined if it would result in persons taking an online diabetes risk assessment and seeking risk reduction information from the Pittsburgh Regional Initiative for Diabetes Education (PRIDE) website and participating in community-based prevention interventions.

Hypotheses

Targeted and sustained messages regarding lifestyle changes and improvement of health will result in persons taking part in programs to improve their health if offered in a modality that fits their lifestyle.

Study Design

A systematic, evidence-based approach was organized to develop the diabetes prevention awareness campaign. This comprehensive approach was divided into 7 phases.

Phase 1: RFP and Agency Selection

The first step in the campaign development process was to issue a Request for Proposal (RFP) to Pittsburgh-based, marketing communications agencies with experience in developing successful social marketing campaigns. The RFP was sent to 11 local agencies. RFP responses were evaluated on 5 key aspects including: project approach, previous work experience on similar projects, staff knowledge and expertise, account service fees, and references.

Phase 2: Situational Analysis

Through a situational analysis, goals of the project were defined; research on diabetes and related topics, such as obesity, were thoroughly reviewed; and existing diabetes-specific campaigns, as well as numerous high-profile non-diabetes social marketing campaigns, were reviewed.

Phase 3: Secondary Research
Through the secondary research analysis phase, several key insights were revealed. The key elements of Self Determination Theory and Behavioral Economics were closely aligned—particularly as they relate to health decisions. The study team could not rely on consumer perception of their own risk to motivate their decision to attempt the risk assessment. Therefore it was needed to draw them in by means other than considering their own risk.

Phase 4: Advertising Concept Development
Based on the key insights garnered from the secondary research, the creative team at Big Picture Communications (BPC) was charged with developing a creative concept that:

- Created interest and intrigue to drive PA residents to an online diabetes risk assessment.
- Was directly responsive to the most current practices and understanding of both social behavior and economic behavior theory.
- Had the capacity to be implemented in a way that will maximize participation in the very diverse urban and rural areas.
- Had the capacity to extend in scope to apply to a national audience or similar target audience.
- Was responsive to the media use patterns of the target audience.

Phase 5: Concept Testing and Results
The three eligible creative concepts were tested to assess their effectiveness in creating interest and driving people to the campaign website. The testing also explored the likelihood of people completing the diabetes risk assessment.

Phase 6: Media Selection
With the intent of the campaign designed to drive the target audience to an online diabetes risk assessment, it was imperative to devise a strategically sound media plan. As with all steps of the campaign development process, media was evaluated and selected based on a thorough understanding of the behaviors, preferences and attitudes of the target audience—both rural/small town and urban.

While the original intention was to run all campaign media for a 12-week timeframe in order to accomplish the necessary “buzz” frequency levels that were needed for a campaign of this nature, the media plan was strategically condensed to be more heavily concentrated over an 8-week timeframe.

Additionally, it was strategically chosen to run the campaign in the fall, as the market responds best to that specific timeframe.

Phase 7: Website Development and Program Enrollment
As the intent of the campaign was to drive at-risk individuals to an online diabetes risk assessment, much emphasis was placed on the development of the campaign website. Not only did the campaign website have to correspond with the campaign materials, but it also had to be entertaining and motivating enough to encourage the target audience to engage in the next steps—taking the online risk assessment and seeking risk reduction information from the PRIDE website—a consumer educational website facilitated by UPDI.

Results
Numerous media campaigns were deployed to heighten awareness and alert communities to the seriousness of chronic disease and its complications. The overarching goal of the media campaign project was to create materials and messages that captured the public's interest in learning about their diabetes risk and seeking subsequent risk reduction information and to devise a methodology that can be applied to other communities.

Overall, the approach was successful in helping to develop effective campaign messages that motivated at-risk individuals to complete the online diabetes risk assessment. Over the 8-week timeframe:

- Over 64,000 individuals visited the campaign website and 38,000 individuals completed the diabetes risk assessment.
- The campaign website was viewed in several counties outside the US, as well as in all 50 states. This was due to the social media component of the campaign website that encouraged participants to pass the website on to a friend.
- 74% of the individuals who completed the risk assessment had a moderate or high risk score.
- 38% of individuals had a high risk score, but only 12% perceived their risk to be high.
- Television was the most effective means of driving participants to the campaign website.
- Only a small number of participants completed the risk assessment and then went on to seek risk reduction information from PRIDE. However, there has been increased traffic to the PRIDE website since the campaign has ended.

- The majority of participants, 55%, were male. It was suspected that the focus on sports programming in the media buy was what helped engage male participants.

- The campaign successfully engaged the 18-54 year olds. 51% of those who completed the risk assessment were between the ages of 25-54 years, 75% were between the ages of 18-54 years. The campaign engaged the 18-24 year olds at nearly twice their representation in this market.

- 89% of those who completed the risk assessment were Caucasian and 6% were African American.

Conclusion

Through campaign feedback, it was found that additional uses of the campaign need to distinguish that the diabetes risk assessment pertains to risk for type 2 diabetes, not type 1 diabetes. Additionally, revealing the specific risk factors that can be contributed to a participant's diabetes risk score may have proved valuable.

The systematic approach used to develop the diabetes prevention awareness campaign and the lessons learned from the research are applicable in the deployment of future health-specific campaigns and not limited to diabetes. Though the findings of the campaign were specific to this market, the methodology used could be generalized to other communities.

Several limitations were also recognized:

None of those surveyed as part of the REACT study identified the campaign as a motivational factor for them to attend the diabetes prevention screening. Several factors contributed to this lack of response. First and foremost, over 4 months passed between the conclusion of the campaign and the REACT screenings. The gap in time may have resulted in a disassociation with the diabetes prevention campaign. Due to unforeseen changes in the study timeline, the campaign did not directly correspond with the prevention intervention screenings. In order to reach the greatest number of individuals over the 8-week campaign, there was a need to select the highest ranked television timeframe for the market (September – November 2009).

Self-reported information must always be interpreted with caution. Individuals are known to either a) identify themselves as the main motivational factor, when ultimately it was driven by an outside occurrence or b) identify the last thing they remember, even if it wasn't the main motivational factor.

Deliverable 2.2.9

Purpose

To determine what motivates consumers to seek out risk reduction information after completing an online diabetes risk test.

Hypothesis

Targeted and sustained messages regarding lifestyle changes and improvement of health will result in persons taking part in programs to improve their health if offered in a modality that fits their lifestyle.

Study Design

Two methods—in-depth telephone interviews and an online survey—were used to engage respondents in a follow-up qualitative survey in order to learn what motivated them to seek out risk reduction information. The online survey was added in an effort to reach a larger number of people than would be possible through the in-depth telephone interviews alone.

To ensure that all interviews were conducted in a consistent manner, a script was developed. The script outlined the approach to the interview process, the tone to be used—one that was warm, friendly and conversational—and the specific questions to be asked. While all of the questions were asked in an open-ended manner and the respondents were asked to self-report, each question on the script was followed by potential answer choices. It allowed for the data to be easily quantified. The intent was to not lead the respondents in any way during the course of the interview.

In addition to the in-depth telephone interviews, an online survey was conducted using Survey Monkey. Survey Monkey is the world's leading provider of web-based survey solutions. Survey Monkey allowed researchers to design customized surveys, collect the responses and analyze the data. The online survey was added in an effort to reach a larger amount of people than would be possible through the in-depth telephone interviews alone. As the same individuals who participated in the online risk test were targeted, it was felt that likelihood of motivating those same individuals to participate in a follow-up online survey could be improved.

Results

During the course of the telephone interviews, 700 individuals were contacted and 107 agreed and qualified to participate in the follow-up interview. This equated to a rate of return of 15.3% which falls within the national telemarketing average of 10-20% response rate [30].

An email invitation to participate in the online follow-up survey was sent to 5,123 individuals. While a total of 558 individuals, or 10.9%, chose to participate in the online survey, only 361 individuals, or 7%, were able to continue after the first qualifying question—"Do you remember going to a website

and taking an online diabetes risk test this past fall that gave you information about your risk for type 2 diabetes?" The results are pleasing t as they exceed the average market research response rate of 4.1% [31].

Conclusion

In an effort to better understand what motivated consumers to seek out risk reduction information and understand why more test takers did not take action after receiving their diabetes risk score, a qualitative survey was conducted.

Both survey groups indicated that a family history of diabetes was the primary motivator for taking the diabetes risk test Participants reported that they had high rates of immediate and extended family members who had either died from diabetes, been diagnosed with diabetes, or were in a pre-diabetes state. Many indicated that having a family history of the disease caused them concern about developing it at some time in their life.

The majority of those surveyed reported that they did not take action after receiving their risk score. When asked why they did not take action, 47% of telephone participants and over 35% of the online participants reported that they received a low risk score and believed they were already maintaining a healthy lifestyle.

Although those who did take action after receiving their risk score did not report enrolling in a formal diabetes prevention program, they did engage in risk reduction activities such as modifying their diet, exercising and seeking out health information online. As the family or knowing someone with diabetes played a key role in motivating participants to take the risk assessment, it also played a key role in motivating participants to take action after receiving their risk score.

The following limitations of the project were recognized:

Self-reported information must always be interpreted with caution. Individuals are sometimes known to identify the last thing they remember even if it wasn't the main motivational factor.

The follow-up survey and evaluation process occurred 7 months after the advertising campaign. This gap in time may have resulted in a disassociation with the diabetes prevention campaign and any action the participants may have taken thereafter.

Focus Area 2: Goal 3

Implement primary prevention efforts to service regional and remote military healthcare facilities.

Deliverable 2.3.34

Purpose

UPMC would implement GLB modalities, specifically the GLB Face-to-Face and GLB DVD/CD-ROM, as programs at WHMC and identified outlying bases.

Hypotheses

Hypothesis : Expansion and provision of a mDPP, referred to as the GLB program, delivered through one of two evidence-based methodologies (GLB face to face or GLB-DVD) at several military health care facilities in the US will (1) increase the number of people screened for the MetS (2) improve control of body weight and MetS parameters.

Study Design

Participants who met screening criteria and expressed interest in participating in the intervention phase were enrolled in a 3 month GLB program. The program consists of 12 sessions delivered over the course of 12 weeks. The intervention focused on healthy food choices, fat and calorie intake, and physical activity. Program goals for participants were to achieve and maintain a $\geq$ 5% weight loss and to progressively increase physical activity to 150 minutes per week of moderately intense activity. Participants were asked to self-monitor food intake and physical activity and were given feedback concerning progress. The intervention was delivered by either of two methods: face to face group classes or through use of the GLB DVD.

Trained lifestyle coaches, or "preventionists," were responsible for delivery of the GLB intervention. Preventionists were required to attend a two-day training workshop, conducted by the University of Pittsburgh DPSC, which addresses all aspects of the GLB intervention. In addition to preventionist training, the DPSC offers "master trainer" training for experienced lifestyle coaches (also referred to as "Train the Trainer" training). An individual who completes the "master trainer" training is qualified to host GLB training workshops and train preventionists.

Anthropometric measurements (height, weight, blood pressure, and waist circumference) were collected by preventionists at screening and three month reassessment. Preventionists ordered participant labs (fasting glucose, triglycerides, and HDL cholesterol) through the Composite Health

Care System (CHCS) one at screening and three month reassessment. The satisfaction survey was adapted from a survey used in past GLB programs and administered at the close of the intervention at 12 weeks.

Results

Data was analyzed on 32 participants in the face to face GLB and 55 in the GLB DVD interventions. Thirty four participants originally enrolled to participate in the GLB face to face intervention; 59 participants enrolled in the GLB DVD, but 2 and 4 participants, respectively, were subsequently removed since they had a documented glucose level >126mg/dl, which is indicative of a diabetes diagnosis. The physician was made aware of the elevated glucose levels.

Participants in the GLB Face to Face program had a significant improvement in weight and BMI, with trends in improvement with reductions in other diabetes risk factors (waist circumference and HDLc). Those participating in the GLB DVD intervention had significant improvements in weight, BMI and waist circumference with trends in improvement for other risk factors (systolic blood pressure (BP), waist circumference, fasting blood glucose and HDLc). Participants in general rated high satisfaction with the program and agreed that the GLB interventions were useful and the information provided was helpful. GLB training workshops were hosted at 3 military sites, affording the opportunity for sustained GLB training and program opportunities for military dependents.

Limitations in program delivery that influence the generalizibility of these findings included a small sample size, missing data and participant attrition over time. It is recommended that these challenges be addressed so that the evidence-based GLB program can be disseminated through trained military representatives to those at risk for type 2 diabetes.

Conclusion

Strengths

- Recruitment improved when GLB implemented as a program as compared to past efforts (i.e. controlled research studies).
- Captain Lisa Strickland's involvement improved military provider awareness of the GLB program at WHMC and surrounding clinics
- Utilizing CHCS I improved recruitment, as providers could order consults for the GLB program
- Participants in general expressed satisfaction with the GLB program
- Participants lost weight
- High attendance at GLB training workshops indicated military-wide interest in GLB program and presents opportunity to disseminate throughout the military
- GLB interventions can be used as an evidence-based weight loss program and diabetes prevention program for military active duty and dependents

Weaknesses

- Limited time available for long-term follow up
- Participant attrition increased towards the end of the program
- Unanticipated challenges encountered implementing GLB program at outreach bases

Deliverable 2.3.38 Appendix – PARC Updates

Purpose

The Physical Activity Resource Center for Public Health (PARC-PH) website (www.parcph.org) was developed in order to satisfy a need for a center that can provide up-to-date physical activity assessment and intervention information as well as guidance to interested researchers and community members.

PARC-PH provides a comprehensive online informational resource regarding physical activity assessment tools and lifestyle intervention materials in an effort to assist individuals in making an educated selection for their assessment and intervention purposes.

Since its inception, the PARC-PH has developed and maintained a vast database (20,000+) of research articles focusing on subjective and objective physical activity assessment. With the continual changes and new developments in the field of physical activity, such as the recent focus on sedentary behavior and physical function, PARC-PH has expanded, updated and enhanced their searchable databases. Specifically, PARC-PH updated and enhanced the search capabilities of the physical activity database. In addition, PARC-PH expanded the physical function database and added sedentary behavior assessment tools and references.

Results and Conclusions

1. Expand and update the current PARC-PH physical activity assessment and intervention tool database

The project investigators updated and expanded both the subjective and objective assessment tool databases of the PARC-PH website, and added information, materials, and supporting literature to aid users interested in the assessment of physical activity. The following was updated:

- Self-Report Measures Search Pages Update: http://www.parcph.org/subjSearch.aspx
- Objective Measures Update: http://www.parcph.org/objSearch.aspx

2. Continue to expand and update the current PARC-PH physical function assessment and intervention tool database by adding assessment and intervention instruments.

The project investigators updated and expanded the PARC-PH physical function assessment tools, search pages, and supporting literature to aid users interested in the assessment of individuals that function at lower activity levels such as older adults or those injured in military and non-military situations. The following was updated or added:

- Self-Report search page: http://www.parcph.org/subjmeasuressearch.aspx
- Performance Based search page: http://www.parcph.org/performancetestsearch.aspx

3. Expand PARC-PH to include Sedentary Behavior

Sedentary behavior is becoming an important component of physical activity and the health equation. Sedentary behavior refers to activities that do not substantially increase energy expenditure above resting level and includes activities such as sleeping, sitting, lying down, watching television and other forms of screen-based entertainment. Similar to both physical activity and physical function, sedentary behavior can be assessed by self-report (questionnaires/diaries/logs) and objective measures (accelerometers/inclinometers).

The project investigators created sedentary specific self-report and objective measure pages for the PARC-PH website, which focus on the definition and descriptions of what constitutes sedentary behavior (Self-Report: http://www.parcph.org/sedentaryselfdesc.aspx; Objective Measures: http://www.parcph.org/sedentaryobjdesc.aspx).

4. Retool PARC-PH website to include glossary of commonly used terms in the area of physical activity and physical function and provide a matrix of fundamental questions to guide user in selecting an assessment tool. The following was updated:

- Glossary of Terms: http://www.parcph.org/glossaryofterms.aspx
- Selecting a Tool Matrix: http://www.parcph.org/selectingatool.aspx

5. Create a links section to include related links to publically available SAS (statistical analysis system) codes to assist with accelerometer data analyses and other physical activity or public health related organizations

The project investigators updated the PARC-PH website existing links page (http://www.parcph.org/links.aspx). Links to the National Cancer Institute's SAS Programs for Analyzing NHANES 2003-2004 Accelerometer Data and other data sets has been added. Additional links added to PARC-PH include but are not limited to: US Physical Activity Guidelines for Americans

which provides information on the Federal Government's guidelines for physical activity; American College of Sports Medicine, Compendium of Physical Activities, a site designed to provide the updated 2011 Compendium of Physical Activity MET codes; and Sedentary Behaviour Research Network, an organization that provides information to researchers and health professionals interested in the health impact of sedentary behavior.

6. Additional Updates:

In addition, PARC-PH added the capability to sort search results by author and year as well as link out to Google Scholar. Linking out to Google Scholar allows for PARC-PH users to gain access to publically available full-text articles that are related to or have cited primary references in the PARC-PH database. Google Scholar opens opportunities to PARC-PH users with limited library options by gaining access to materials available on the worldwide web.

Deliverable 2.3.35 Appendix – GLB Training

Purpose

The purpose of the additional GLB training was to provide training for military health professionals in delivery of the GLB program and to promote sustainability of the model by developing and offering a Master Training course to allow military Master Trainers to deliver ongoing training within the military.

Results and Conclusions

GLB Workshops

DPSC faculty worked with USAF partners to determine optimal sites for onsite GLB training workshops within the military. Two training workshop sites were identified: San Antonio, Texas and Arlington, Virginia. These sites were chosen based on the proximity of the sites to large military bases. DPSC faculty worked closely with the military partners to develop workshop marketing materials and to determine best strategies to disseminate these materials to engage military health professionals in participating in a training workshop.

Two GLB training workshops were held: 1) in San Antonio on September 12 and 13, 2012 and 2) in Arlington on October 23 and 24, 2012. A total of 49 health professionals participated in the training workshops. The largest number of attendees was from Lackland Air Force Base (AFB), Texas, followed by Fort Sam Houston, Texas and Joint Base Andrews AFB, Maryland.

Program Delivery

Workshop attendees were queried as to whether they plan to implement the GLB program within the next year. A total of 48 attendees responded to this question. Of that number 30 (63%)

responded that they intend to provide, or are already providing the GLB program, 14 (29%) indicated that they do not plan to implement the program in the upcoming year, and 3 were unsure. Responses regarding reasons for lack of implementation were received by 13/14 participants. Reasons they did not plan to implement the program, included lack of funds/resources 9 (69%), lack of leadership support/ commitment 2 (15%) and concern about lack of participant commitment.

Barriers to delivery of the GLB Program

For those who responded that they planned to implement or were already implementing the GLB program, barriers to implementation are provided in Figure 2 below. The primary barriers reported were issues related to funding, and general resources such as lack of staff and space. Other concerns included participant commitment, lack of leadership support, recruitment, cost effectiveness of the program, and scheduling issues. A desire for a similar healthy lifestyle for children/teens was also expressed.

Satisfaction with the GLB training workshop and suggestions for improvement

Participants were asked to rate various aspects of the workshop on a scale of 1 to 5, with 1 reflecting an answer of "Not at all" and 5 reflecting an answer of "To a great deal". In addition, participants were asked to provide a rating of the overall workshop, again using a scale of 1 to 5, with 1 reflecting an answer of "Poor" and 5 reflecting an answer of "Excellent". Workshop attendees rated the GLB training workshop overall very highly, with a rating of 4.8.

Only a few suggestions were received for improving the GLB workshops. These were suggestions such as providing a focus on the complications of diabetes, further review of the GLB leaders guide and handouts and more focus on how to apply group facilitation techniques.

GLB Master Training

The DPSC investigators worked initially to develop a Master Trainer Web Portal, which is housed within the existing Health Professionals Portal on the DPSC website. The link will only be provided and visible to those only be accessible to those who have successfully completed the Master Training workshop. The Master Trainer component of the website will include all of the presentations, handouts, and other materials that are needed to deliver a GLB workshop for health professionals. Thus it will facilitate ensuring that all GLB Master Trainers are using the most up-to-date materials and will also ensure that the materials being utilized are standardized.

The portal will provide a resource for Master Trainers for workshop materials, presentations, handouts, etc. and will be designed for those individuals trained as Master Trainers and accessible via a username and password. This will facilitate the Master Training process, allowing GLB Master Trainers to network for the sharing of knowledge and resources.

The DPSC worked with the Air Force Medical Service (AFMS) military partners to identify appropriate military professionals to be trained to become GLB Master Trainers. Master Trainer qualifications include the following:

- Completion of previous GLB training workshop
- Experienced in delivery of the GLB program to participants (must have delivered at least one full series of GLB)
- Recommendation for Master Training by military supervisor

A total of 7 military health professionals applied to attend the GLB Master Training, and 5 were accepted to participate. Additionally, 5 civilian health professionals attended the workshop. The GLB Master Training workshop was conducted over a two day period on January 16 and 17, 2013. A GLB Master Trainer Guide and Workbook was created by the DPSC faculty, which includes 1) all of the power point presentations that are covered in the GLB provider workshop, with specific notations added to each slide to assist the Master Trainers in delivery of future workshops, and 2) a summary of key points for Master Trainer consideration when providing a training workshop.

Reported Anticipation of Provision of Future Training Workshops

Nine out of 10 workshop attendees indicated that they plan to offer a GLB Training Workshop within the next 6 months; this number included all 5 military attendees. Some barriers to workshop provision reported by military workshop attendees included:

1) Concerns about staff being able to take off time for the 2 day workshop.

2) Master trainer time to prepare for the workshop, as well as the time involved in delivery and evaluation of the workshop.

3) Getting materials printed and loaded into notebooks.

Workshop Evaluation

At the conclusion of the Master Training workshop, attendees were asked to complete an evaluative survey (scale of 1-5). In general, all comments were very positive; however one concern was related to the time allotted for training. It was suggested by several that more time was needed and that the workshop should be conducted over a 2.5-3 day period. Suggestions included the possibility of asking individuals to review some of the material prior to the workshop in the future to save on time at the workshop. Other suggestions focused on providing more information regarding specific coaching techniques and coach skill building.

Recommendations

Important information was ascertained from the workshop attendees through delivery of this GLB Master Trainer workshop. The DPSC will continue to develop and grow the training based on the feedback provided. As efforts continue to further develop a diabetes prevention program for the

military, the training will serve as a prototype for future Master Training workshops, and will allow the DPSC to continue to develop and maximize the provision of this training for the military and civilian populations.

It is strongly recommend to develop a training and support center for GLB provision within the AFMS in order to provide a standardized program for optimum implementation and results throughout Military Treatment Facilities across the US. There are now an additional 5 GLB Master Trainers who will be able to provide GLB training for health professionals affiliated with the AFMS and other branches of service. These workshops will provide a basis for sustainability of the GLB program within the military setting; however we must continue to move forward with other options for training, including the online GLB training that will be available in 2013.

Focus Area 3 - Diabetes Treatment in the Chronic Care Model (CCM) Framework

It has been demonstrated the effectiveness of using the CCM organized around elements (health system, community, decision support, clinical information systems, self-management, and delivery system design) to improve both clinician processes and patient outcomes in a variety of health care settings. In communications with the "creators" of the CCM and the Pennsylvania Governor's Commission on Chronic Disease, it was learned that although the CCM has had widespread adoption, key questions remain unanswered. The following hypotheses were developed in response.

Focus Area 3: Goal 1

To continue to evaluate methodologies in the implementation of the CCM in diverse populations in community settings and practices.

Deliverable 3.1.11

Purpose
The overall objective of the study was to determine the most effective and efficient method of adopting the CCM in diverse primary care practices.

Hypotheses
Hypothesis: Sequential implementation of the CCM will result in improved clinical and process outcomes and provider and patient satisfaction compared to comprehensive implementation.
Hypothesis: Providing a practice coach will enhance efficiency in adoption of the CCM compared to practices not utilizing a practice coach.

Study Design
The PRIDE diabetes educators recruited primary care physician (PCP) practices in Western Pennsylvania Counties. These communities are socioeconomically depressed areas, and/or rural communities. Thirteen primary care practices participated in the study, including five practices in rural counties (Cambria, Fayette, Indiana, Washington, and Westmoreland).

All of the PRIDE sites exist within their own Health Systems within their communities. None of these sites are associated with UPMC. The PRIDE sites exist within communities in the 5 counties named above. All PRIDE sites were encouraged to work with their community partners (YMCA, philanthropic organizations, Community Action Organizations). PRIDE sites are conducting physical activity events, grocery store tours, cooking demonstrations, and health fairs to increase diabetes awareness and appropriate care.

Decision Support, in the form of guidelines, applies to DSME programs physicians under the Standards for DSME [32] and the ADA Standards of Medical Care [33]. The most common thing that impacted Decision Support was the adoption of flow sheets in the practices. These flow sheets allowed practitioners to track patient data over time to see trends in outcomes. All of the DSME programs adopted *Chronicle* as their Clinical Information System to support their education programs. Of the 13 primary care practices participating in the study, only 5 have electronic health records. The flow sheets allow providers to examine data longitudinally, so for now, this serves as an information system. This will help them in the future if they decide to adopt an electronic health record as data will already be recorded and ready for entry. The primary care providers in this study adopting this element are facilitating DSME in their practices as a method of Delivery System (Re) design. This increases access to DSME, saves patients time, and provides an opportunity for the diabetes educator to act as a resource for the practice.

Results

Discussion groups were conducted with staff and providers in 13 primary care practices with a large number of patients with diabetes. Groups ranged in size from three to five and included physicians, office managers, licensed practical nurses (LPNs), and medical assistants. A total of 49 health care providers and office staff participated across the 13 practices. When practices were asked to prioritize elements of the CCM for implementation, all but one practice was able to do this. The practices recognized the need for improvement in diabetes care and identified strategies for implementation in a stepwise fashion.

Monitoring the sequence of adoption of the CCM in primary care is feasible, albeit cumbersome. Results demonstrated that the most frequently desired CCM elements to adopt were Community, Self-Management Support and Decision Support. These elements were likely prioritized due to the need for increased access to diabetes education which included having the educator on site in the primary care site. Further, Decision Support was also prioritized based on the providers need to track patient data and adherence to practice standards, while Clinical Information Systems and Health System were the least frequently prioritized likely to the lack of control over implementing these elements.

A common barrier identified from the "Diary of Adoption" was that engaging the administration at the Health System level early on and obtaining the support from this is found to be crucial for success of a sustainable program. Administrative inertia would need to be overcome in order to establish business model for sustainability of DSME services.

Practice coaches facilitated adoption of Delivery System Design/Self-Management Support elements. Their expertise allowed educators in rural sites to rely on those who had significant experience in troubleshooting the introduction of diabetes education in practices. Having this

expertise available to providers as issues arose was also important in order to address barriers in real time.

Conclusion

The study demonstrated that PCPs were able to identify elements of the CCM that they were interested in implementing. They were able to prioritize, and with appropriate resources, implement change. Implementation of the CCM that was practice-based and provider-centered resulted in improvements in blood pressure and lipid control but not A1C. The changes observed in blood pressure and lipid were statistically significant but likely not clinically significant.

Not all goals were achieved for improvement that was hypothesized in the proposal. There may be several reasons for this. Implementation of process change requires time. Practices were asked to implement change over a one year period. Although changes were observed, follow-up time was not long enough to observe clinically significant change. A decline in A1C was not observed. The average A1C in this population did not have a poor glycemic control (average 7.4%) at baseline; therefore, there was not much opportunity for improvement. A sensitivity analyses was conducted on those who had A1C >7% and had medication intensification. Given sufficient follow-up and an average decline of 1.5% which was reported in a recent meta-analysis, the differences would be statistically significant.

Comprehensive implementation of the CCM was conducted between 2000 and 2003 in an underserved suburb of Pittsburgh [34]. A 0.6% significant decline in A1C was observed in that study. However, the patients in these analyzes were also undergoing a diabetes education intervention at the same time. Therefore, the cause and effect of the physician piece of the intervention could not be determined. The current study allowed project team members to examine an implementation of the CCM without simultaneous patient intervention. Given the results, it is likely that a patient intervention using DSME may result in more significant change.

There was little influence on clinical data by use of practice coaches. The practice coaches primarily were consulted on process changes which included reimbursement structure, group visits, implementation of diabetes days, and tracking data. It is likely that follow-up time may have been too short to observe the true impact of their intervention on clinical outcomes.

One of the most significant barriers encountered during this study was the lack of buy in from the administration of certain health systems. All of the providers wanted to continue to have diabetes educators in their practices and were very satisfied with the CCM approach. However, administrators were not always willing to prioritize these efforts. Future work should focus on helping administrators understand the importance of these interventions. Without their full support, sustaining DSME in primary care may be challenging.

Overall, this study provided significant insight into the challenges and opportunities available for improving diabetes care in communities. Continued efforts should focus on all elements with a primary focus on administration and interventions with patients with adequate follow-up.

Deliverable 3.1.12

Purpose

The objective of this analysis was to determine if implementing a practice-based provider centered intervention is more cost-effective than usual care.

Hypothesis

Hypothesis: The implementation of the CCM is more cost effective than usual care.

Study Design

Using TreeAge Pro Suite 2009 (TreeAge Software, Williamstown, MA), a prior Markov decision model was modified to estimate the incremental cost-effectiveness of the CCM strategy (i.e., Post-CCM) compared to the usual care (UC) strategy (i.e., Pre-CCM). The model directly incorporated intervention costs and effectiveness data from the CCM study conducted by Dr. Janice Zgibor and her team in the Pittsburgh area to estimate life expectancy, quality-adjusted life-expectancy (expressed as quality-adjusted life-years, or QALYs), clinical outcomes (diabetes with chronic complications), as well as direct medical and nonmedical costs associated with the intervention strategies (CCM vs. UC). In the model, a base case was used from the health care system perspective, which examined 62-year-olds with type 2 diabetes who participated in two intervention strategies in yearly cycles over a 20-year time horizon. Additionally, it was assumed 100% intervention compliance.

Conclusion

It was hypothesized that implementing the CCM intervention using a practice-based provider centered approach would be more cost-effective than usual care. The findings demonstrated:

- Based on the suggested cost-effectiveness decision rule of modern health care ($100,000-$300,000 per QALY gained), the CCM strategy compared to UC may not have reasonable expenditures associated with gaining QALYs over a 20-year time horizon from health care system perspective ($337,776 per QALY gained) and societal perspective ($461,421 per QALY gained).

- Given the assumption of effective medication intensification for glycemia over a sufficient follow-up period, the CCM strategy may have reasonable expenditures associated with gaining QALYs over a 20-year time horizon from health care system perspective ($114,420 per QALY gained).

Limitations

- Interpretations of study results were contingent on data quality and model assumptions.
- Subjects in this analysis were representative of the community-based population with diabetes, but results may not be fully generalizable to other populations or health care settings.
- Once medication intensification was applied, the results were more cost-effective, however, this should be interpreted with caution as this is hypothesis generating only.
- Previous interventions with a patient component demonstrated greater cost-effectiveness. Therefore the likely next step for this study is to continue the provider intervention and add a patient intervention.

Focus Area 3: Goal 2

Implement elements and evaluate the CCM, as a healthcare delivery model for diabetes in military healthcare facilities

Deliverable 3.2.9

Purpose

The Diabetes Center of Excellence (DCOE) serves as a specialty clinic resource to patients and as a military regional hub for the provision of quality diabetes prevention and treatment programs.

Hypotheses

Hypothesis: Transitioning the Diabetes Outreach Clinic (DOC) from a primary care based clinic to a military DCOE will serve to provide a resource for the provision of quality diabetes prevention and treatment services to the military community.

Study Design

The DCOE team provides specialty diabetes care to type 1 diabetes (T1D) and type 2 diabetes (T2D) patients who meet specific criteria and serves as a referral center for patients with diabetes not meeting clinical targets. In addition, the DCOE serves as a training platform for WHMC providers and outreach bases.

The outlying military bases serve as community spokes to the regional DCOE hub. The overarching goal was to determine if the spoke outreach sites receive and adopt the diabetes treatment strategies supported by the DCOE. An assessment and implementation group referred to as a "Go Team" serves in a liaison capacity bridging the hub site programs to its spokes. Their role is to facilitate information and support to the sites. They also provide clinical and consultative services on designated days at the bases.

During the course of the DCOE program, patient criteria for admission to DCOE care services were routinely reassessed to assure capacity and appropriate care operations and processes. The criteria are re-evaluated by UPMC and the AF medical team and representatives.

Available DCOE data was retrieved from the Military Health System Population Health (Population Health) Portal from AF/SGRKP. Go Team data was extracted from the AHLTA military health system. Provider and patient satisfaction surveys were designed and distributed to patients and providers at the DCOE and participating outreach sites.

Results

Among these 1,816 patients who received care in the DCOE, mean age was 57 (SD: 11.3) years and 996 (54.85%) were male. Of these patients, 545 (30.01%) were white, 182 (10.02%) black, and 114 (6.28%) other races. The average baseline weight and body mass index (BMI) were 205.13 (SD: 47.96) lbs and 32.39 (SD: 9.29) kg/m^2, respectively. Of these patients, 868 (61.08%) had BMI greater than 30 kg/m^2 at baseline.

Satisfaction Surveys were administered to DCOE patients and providers. Questions were asked on a 1 to 5 likert scale (1 = strongly disagree/poor; 5 = strongly agree/ excellent). An additional 150 surveys were collected from Aug, 23, 2010 to Nov. 12, 2010 bringing the total to 412 surveys.

Twenty- two providers at WHMC who refer patients to the DCOE completed a satisfaction survey. Of the providers surveyed, there are: 9 physician assistants, 8 physicians, 4 nurse practitioners, and 1 nurse. Of the providers who answered the question, "our clinic physicians and nurses benefited from DCOE educational sessions," 9 % strongly agreed with this statement, 32% agreed, and 45% strongly disagreed. Thirteen of the 20 providers who answered the following question agreed (or strongly agreed) that the DCOE helped apply them apply the most recent management strategies to

patients with diabetes. Seventeen (77.3%) providers surveyed agreed (or strongly agreed) that the nurse educator from the DCOE was a helpful resource to this clinic. Twelve of the 17 providers who answered the question agreed (35.3%) or strongly agreed (35.3%) that they are able to communicate a treatment plan effectively together with the DCOE team.

Diabetes is a complex, chronic disease where long-term measurement of clinical outcomes is necessary. Given the challenges with data collection and staffing, and the limited time frame to demonstrate the full impact of a diabetes specialty clinic on diabetes outcomes, the findings from the DCOE service were very encouraging.

From baseline through DCOE follow up, there was a significant improvement in key diabetes clinical outcomes, with a reduction in blood pressure, HbA1C, LDL, and total cholesterol levels. Although the percentage of patients who had HbA1C level < 7% decreased slightly from 38.01% to 37.82%, it was not statistically significant. The percentage of patients who had improved blood pressure, LDL, and total cholesterol levels significantly increased. Although the changes in percentages of HDLc < 40 mg/dl were not statistically significant, trends for improvement were also seen.

Given that this patient population was overweight with more than half (61%) being obese, interestingly patient LDL and cholesterol levels were generally within recommended levels at baseline. Most importantly however, is that diabetes therapies were intensified for those patients receiving care in the DCOE who had glycemic, lipid and blood pressure values that were not within the recommended ADA range. For example, patients on OHA monotherapy transitioned to more appropriate intensified therapies with the addition of insulin and/or combination OHA. A reduction of OHA monotherapy coupled with an intensification of therapies of therapies from OHA only to insulin and combination therapies was statistically significant. Diabetes therapies were also intensified for both lipids and hypertension. Given the trajectory of a chronic disease and risk of micro- and macrovascular complications, the benefits of intensified therapy delivered through a team-based, specialty model has great potential yet to be fully recognized.

Despite limitations, the findings from the DCOE and Go Team efforts were favorable. Trends toward improvements in clinical outcomes were demonstrated. Patient and provider satisfaction with services provided at the DCOE hub and outreach bases at Goodfellow and Laughlin AFB were positive.

Diabetes specialty and team-based care have been shown to have a positive impact on diabetes outcomes [35,36]. As the numbers of people with diabetes continue to escalate, given the humanistic and cost burden, the provision of quality care is critical for military beneficiaries.

Conclusion

Weaknesses

- There was missing follow up data. Therefore, a before and after effect could not be shown in many patients. Since this is a specialty clinic, it may have been recommended that patients not return (problem for which they were referred was resolved), thus the missing follow up data was not available. In other words, patients were successfully managed and graduated from the DCOE services.
- Patient no show rates were high despite efforts to engage patients, such as reminder phone calls made before scheduled appointments.
- Rates for completion and submission of satisfaction surveys are lower than expected despite a mailing to 500 patients.
- There was an assumption that physicians would immediately refer patients to the DCOE. This was not the case and it required several months to engage referring physicians.
- It was not immediately realized that patient criteria for admission to the DCOE services needed to be adjusted and assessed in an ongoing manner.
- It is difficult to know if the DCOE and Go Team model would have been more effective had there been integrated data management systems, staff hires facilitated more quickly, or the clinic model be in place for a longer period of time
- Limited time frame to evaluate a new start up diabetes clinic and model of care delivery.
- Determining the benefits of care provided by a specialty diabetes clinic requires long term follow up.
- Patients did not always adhere to follow up visits. No show rates however are typically high in diabetes specialty clinics where care for the most challenging patient cases is provided.
- Engaging and employing clinical and research staff caused delays despite multiple efforts.
- After staff was hired, there were challenges in preparing them to perform their duties, e.g. credentialing, receipt of Cat cards, delays in computer access.
- In some cases, orientation to roles and responsibilities took longer than anticipated. For example, nurse practitioners may have required additional training in diabetes care.
- Medical Expense and Performance Reporting System (MEPRS) codes are used to identify patients who receive care. However, DOC patients were assigned the DCOE MEPRS code when the DOC transitioned to the DCOE. Thus, it can be difficult to distinguish unique DCOE patients.
- Lack of integrated data systems.
- Competing demands with clinic workload.
- Outreach base staff turnover, new leadership, identifying champions, and establishing relationships with bases.

- Base turnover, changes in leadership.
- UPMC staff turnover, re-engaging new staff for Go Team.

Strengths

- Patient clinical findings from the DCOE and Go Team efforts are favorable. Trends toward improvements in clinical outcomes are demonstrated.
- Patient and provider satisfaction with services provided at the DCOE hub and outreach bases at Goodfellow and Laughlin AFB are generally positive.
- Intensified therapies for glycemic, lipid and hypertension management

Deliverable 3.2.12

Purpose

In order to facilitate the transition of the DCOE to the USAF, a clinical and operational sustainability study was completed.

Program Objectives

The objectives for the DCOE were as follows:

- To achieve status as the military leader for diabetes care and prevention by establishing and disseminating medical and educational standards, evaluating and refining strategic directions, and identifying innovative outreach strategies and evaluation processes.
- To function as a specialty clinic resource for diabetic patients from the active duty, beneficiary, and dependent populations of the military branches at the SAMMC.
- To utilize a multidisciplinary team approach to provide evidence-based specialty diabetes care to T1D and T2D patients who meet specific criteria and serve as a referral center for patients with diabetes not meeting clinical targets.
- To provide a training platform for providers at WHMC and outreach bases.
- To serve as a military regional hub for treatment of complex patients and deployment of quality diabetes treatment and prevention programs.

Conclusions and Recommendations

Upon review of the evolution of diabetes care at WHMC, many successes and accomplishments that have been achieved along the way were recognized. It was also experienced that a variety of barriers and challenges that had obstructed, delayed, or prohibited full realization of the research and programmatic objectives.

Clinical Operations

The DOC was intended to function as a "one-stop-shop" where patients would present for an appointment and receive comprehensive diabetes specialty services. Although the transition from the DOC to the DCOE was necessary to reach more patients, aspects of the DOC patient-centered approach were lost with the transition to the DCOE, resulting in a more fragmented model of care and treatment. Both Primary Care Managers (PCMs) and DCOE providers expressed concern about fragmentation of care for patients. To address these gaps it was recommend that the DCOE focus on enhancing coordination of care to help ensure that services are consistent with the complex needs of diabetes patients, that providers are aware of the services received from other parts of the health system, and supports positive patient-provider relationships.

In addition, to improving the coordination of care, the DCOE is well-positioned to expand their clinical services to better serve their existing patient population as well as extend the reach of prevention efforts to additional population groups. Some ideas for consideration would be to develop a DSME refresher course for long-term diabetics, to offer a group exercise program that teaches patients exercise skills that match their level of mobility, and potentially to re-instate some form of ophthalmic services. In addition, prevention programs could be extended to other groups who would benefit, such as active duty who fail to meet the fitness standards.

Strategic Direction of DCOE

It is recommended that the DCOE continues to utilize metrics to assess the impact of programmatic and clinical performance goals.

- Programmatic: Initiatives aimed at evaluating the DCOE concept of functioning as a specialty clinic resource for diabetic patients from the active duty, beneficiary, and dependent populations of the military branches at the SAMMC. Metrics to measure the effectiveness of the multidisciplinary team approach to provide evidence-based specialty diabetes care and the DCOE's ability to serve as a military hub for treatment of complex patients and deployment of quality diabetes treatment and prevention programs should be monitored and assessed. One recommended programmatic initiative is encouraging DCOE nursing staff that meets requirements to obtain CDE licenses. This will expand the types of services that the nursing staff can provide to patients, which supports staff productivity, cost-effectiveness of staffing model, and, in the event of position vacancies, the potential opportunity to cross-utilize nursing staff in additional roles as needed.

- Clinical quality improvement: Initiatives aimed at continuous monitoring and improvement of patient outcomes. This requires understanding and communicating short and long-term program objectives and establishing quality indicators to drive change. DCOE staff members initiated process improvement activities described in this report, which were consistent with

program objectives. Staff should receive ongoing training and support that increases their capacity to assess, perform, and sustain quality improvement activities.

Information Technology within DCOE

Significant strides have been made towards facilitating efficient and effective diabetes care and management through timely access to relevant patient and population data. Implementation of the Chronic Disease Management Program and the potential of utilizing Chronicle will further enhance these elements.

The IT systems used to support day to day care should be further developed to facilitate patient care and track clinical outcomes, support information exchange and coordination of care among PCMs, the DCOE, and other health care providers, and promote diabetes self-management by patients. We recognize that this recommendation must be considered within the global context of decisions made for advancement of the military's electronic health system.

Hub and Spoke Model

A major concern for the DCOE, like other diabetes programs, relates to the disturbing trends of increasing numbers of diabetic and pre-diabetic patients and chronic shortage of diabetes specialists. Currently in the US, there are approximately 4,000 endocrinologists and 30,000 diabetes educators, only half of which are CDEs, practicing in the clinical setting. According to DCOE leadership, the USAF has 8 practicing endocrinologists and approximately 20 CDEs in dedicated positions, complemented by some additional staffing provided by contracting entities. With an estimated 40,000 active duty and family members, retirees, and spouses with diabetes across the world, the AF health care system faces challenges, similar to those in the civilian sector, in assuring that patients, regardless of their location, receive the same comprehensiveness of care.

The hub and spoke model offers the potential to help remote bases better serve their diabetic patient populations. Although the Go Teams served valuable roles as the liaisons between the hub clinic and outlying spoke sites, the program was found to be resource intensive and logistically difficult to sustain. Telehealth is the electronic use of information and telecommunication technologies to support long-distance care, patient and provider-related education, public health, and health administration [37]. Introducing telehealth models of care has tremendous potential to extend and connect diabetic services to military health care beneficiaries throughout the world. Studies have shown that information and communications technology (ICT) for diabetes care management is feasible, cost-effective, and reliable [38]. Improvements in glycemic control and blood pressure levels, as well as improved self-management have been demonstrated with the use of ICT programs [39, 40]. The AF may want to consider the use of ICT to support some of the functions provided by the Go Teams. Results of the telehealth projects conducted in the civilian population under the FY '07 and FY '09 funding may be useful in informing this process.

UPMC LIFE CHANGING MEDICINE

Deliverables 3.2.14 and 3.2.17 Appendices – Chronicle Updates

Purpose

The National Standards for DSME administered through the ADA ERP provide a framework for standardized delivery. Assuring consistency with a standardized program is particularly important in military-based programs where staff turnover is high and the supply of health care providers is scarce. UPMC, in collaboration with the DCOE, organized an ADA recognized program for the USAF at WHMC, but the process has yet to be implemented at other AF bases. With the rising rates of diabetes, the delivery of quality DSME is critically important.

Chronicle Diabetes data system allows diabetes educators to assess, document, and generate reports regarding both diabetes clinical and self-management data in a single system. On a larger scale, Chronicle is being used by the ADA, as the self-management resource for diabetes education programs across the US. Chronicle Diabetes is a single software tool that allows educators to contribute to a national diabetes repository offers the functionality to monitor and evaluate diabetes self-management in disparate programs across the country. Educators gather, manage, and recall patient information. The system is also used to support the ADA Education Recognition Program (ERP) application process.

Upgrades and Enhancements

Many features of *Chronicle were* updated or enhanced as part of the efforts of Focus Area 3 Goal 2 by Flipside Media, Inc. All of the work described below was guided by ongoing interaction with current *Chronicle* users as well as representatives from the ADA. Flipside held twice-monthly user group webcast calls with between 5-15 educators to discuss the new features, obtain feedback, and ensure that all development was optimized for real-world use. Flipside also conducted weekly webcast calls with ADA representatives to ensure that all development met ADA requirements, recommendations, and best practices. Additionally, all features and functionality were developed to provide a smooth integration between *Chronicle* and the ADA ERP application (which all ADA-recognized programs nationwide use for submission of recognition data).

The following is a list of main improvements with the full list and descriptions included with Deliverables 3.2.14 and 3.2.17:

- Improved question and response content
- Added additional reports
- Implemented education templating
- Improved letter templating
- Improved medications interface
- Improved program management functionality
- Improved initial patient self-assessment form

- Implemented new notices and alerts
- Created a process to include patient assessments before a lesson plan is defined
- Added an education plan to patient's profile
- Removed requirement for medication dose and frequency
- Created a patient record form that is printable
- Added patient follow up to educational stages status options
- Improved to display class notes on individuals patient's notes section
- Allowed patients to be associated with multiple sites within a program
- Added units to all clinical data and lab values
- Added additional questions to self-assessment
- Revised education follow up interface
- Added documentation for Quality of Life, Patient Satisfaction
- Added DSME follow up report
- Added ERP data report
- Created screencast/tutorial for Chronicle portal
- Created secure web service for communications with other systems

Deliverable 3.2.15 Appendix – ADA Recognition

Purpose

The National Standards for DSME administered through the ADA ERP provide a framework for standardized delivery. Assuring consistency with a standardized program is particularly important in military-based programs where staff turnover is high and the supply of health care providers is scarce.

UPMC, in collaboration with the DCOE, organized an ADA recognized program for the USAF at WHMC, but the process has yet to be implemented at other AFBs. With the rising rates of diabetes, the delivery of quality DSME is critically important. UPMC and investigators at the University of Pittsburgh proposed to work with military partners to provide support to identified AFBs pursuing ADA Recognition.

Summary

The WHMC DCOE, with assistance from UPMC under cooperative agreement W81XWH-07-2-0080, applied for and received ADA recognition in May 2007. The DCOE has maintained their status as an ADA recognized site since that time. As such, the DCOE is familiar with the processes required to apply for and maintain recognition.

In collaboration with AFMSA/SG9S, Wright-Patterson AFB (WPAFB) was identified as a site that could pursue ADA recognition. Preliminary discussions with Wright-Patterson regarding the application process began. After further consideration, however, the WPAFB diabetes leadership indicated that they could not reallocate personnel time from clinical duties to pursue recognition.

Through multiple discussions with Andrews AFB, the AF, and UPMC, the diabetes team at Andrews AFB decided to proceed with the ADA ERP application process. The University of Pittsburgh, specifically Linda Siminerio, PhD and Kim Huber, MPH, provided ongoing support during the recognition process. While a formal training program was not developed for this effort, University of Pittsburgh personnel provided ongoing administrative support and guidance to the Andrews AFB diabetes team. Andrews AFB submitted their ERP application on November 30, 2012 and is pending approval by the ADA.

Focus Area 3: Goal 3

Develop planning proposal for research and development towards the development of a portable retinal imaging system and real time informatics system to provide automated decision support for diagnosis and appropriate eye care.

Deliverable 3.3.7

Purpose

The primary objective of this self-administered non-mydriatic retinal camera (SNARC) Image Validation Study is to test the hypothesis that retinal evaluation using non-mydriatic digitized images obtained through the SNARC imager exceeds or matches the quality of Early Treatment Diabetic Retinopathy Study (ETDRS) 7 standard field 30^{o} color stereoscopic fundus imaging.

Hypotheses

Hypothesis: The development of a portable retinal imaging system and a real time informatics system will provide automated decision support for diagnosis and appropriate eye care.

Proposed Study Design

This study was designed as a single-center, masked multiple reader, diabetic retinopathy validation study. All readers would be certified according to ETDRS reader center protocol using Wisconsin reading center templates. Patients would have their retinas imaged using two different imaging strategies. Each image set would be randomly assigned to different readers; image sets could be assigned to the same reader multiple times. Discrepancies between

reader's findings would be resolved by an independent adjudicator. All statistical comparisons would be performed using unweighted Kappa statistics to determine inter- and intra-reader levels of agreement and chi squared analysis of contingency tables to test the hypothesis that there is no significant difference between the SNARC imaging strategy and ETDRS 7 standard field 30^{o} color stereoscopic fundus imaging to diagnose accurately the level of retinopathy.

Interim Analysis for Validity

Every month results would be evaluated to determine if any particular imaging strategy warranted further investigation. Planned and unplanned interim analyses would be conducted under the auspices of the Data Monitoring Committee. Only the Data Monitoring Committee would be authorized to review unmasked interim validity. If necessary, the Data Monitoring Committee could recommend early termination of one or more imaging strategy.

Screening and Baseline Comparisons

Patient characteristics obtained during the validation study would be listed and summarized. The summarization will include descriptive statistics (mean, standard deviation, and percentiles) for continuous variables, and frequencies and proportions for categorical variables. For Gaussian variables, such as age, Analysis of Variance (ANOVA) techniques would be applied, using clinical center and type of diabetes as blocking variables to increase precision. A check will be made for normality and constant variance. Nonparametric procedures would be applied as appropriate. For discrete variables, such as gender and race, Cochran-Mantel-Haenszel procedures would be applied, using clinical center and type of diabetes as blocking variables.

Confounding Events and Competing Explanations

Validation would be summarized by imaging strategy. Examiner, photographer, and reader compliance to ETDRS protocol would be monitored.

Image Specific Analysis

As described above, all images would be read and compared to ETDRS 7 standard field 30^{o} color stereoscopic fundus imaging to diagnose accurately the level of retinopathy. Information from this analysis would be summarized, including descriptive statistics (mean, standard deviation, and percentiles) for continuous variables, and frequencies and proportions for categorical variables. Statistical comparisons across the imaging strategies would be performed. For Gaussian variables, ANOVA techniques would be applied. For categorical variables Kappa statistics would be used to determine inter and intra reader levels of agreement. Chi squared analysis of contingency tables would be used to test whether or not there is a difference in level

of retinopathy diagnosis using ETDRS 7 standard field 30^{o} color stereoscopic fundus digital imaging as the gold standard and level of retinopathy using the SNARC imaging system.

Subject Satisfaction

Subject satisfaction would be analyzed by exit questionnaire administered by the study coordinator to compare patient comfort for each of the imaging strategies.

Subgroup Comparisons

Each of the SNARC image strategies (single field stereo non-mydriatic, single field stereo and two addition non-stereo fields non-mydriatic, and SNARC nonmydriatic imaging centered on each of the ETDRS 7 standard fields) would be compared to the ETDRS 7 standard field 30^{o} color stereoscopic fundus digital imaging.

Statistical Analysis

The primary endpoint would be demonstrating that SNARC images (single field stereo non-mydriatic, single field stereo and two addition non-stereo fields non-mydriatic, and SNARC nonmydriatic imaging centered on each of the ETDRS 7 standard fields) are not significantly different from ETDRS 7 standard field 30^{o} color stereoscopic fundus digital imaging. Kappa analysis will measure inter- and intra-reader levels of agreement. Chi-squared analysis would measure differences in retinopathy levels assessed by imaging modalities.

Focus Area 4 Inpatient Initiatives Glycemic Management protocols

Incidence of diabetes (2.03 per 1000 person-years for individuals between the ages of 20 and 44 in the AF) among the active-duty military population parallels that observed in the general population [41]. With the increased rates of diabetes, one can expect that hospitalization rates for military dependents and retirees will also be similar to what is observed in the general population and a program of targeted inpatient glycemic management will offer similar benefits. Under the heading *Operations Other Than War,* the Military Health System MHS outlines (http://mhs2025.sra.com/index.html) a plan to develop a comprehensive health strategy for diabetes and related complications in enlisted personnel, retired personnel and their dependents. The military holds itself to civilian standards of medical care, including standards recommended by the ADA and the American Association of Clinical Endocrinologists for outpatient and inpatient diabetes management [42, 43]. There is an urgent need to standardize the monitoring and intervention practices for hospitalized patients presenting with diabetes as a primary or secondary medical problem or with newly recognized hyperglycemia as a means of improving outcomes and reinforcing patient compliance with diabetes self-management. The importance of instituting protocols for inpatient glycemic management extends to the future care of patients in the military. The development and implementation of strategies for inpatient management with evaluation of their impact on outcomes and health care costs will allow for the ready transfer of this information to military hospitals.

Focus Area 4: Goal 1

Implement inpatient management protocols and continue to investigate and evaluate effectiveness of protocols at WHMC with support from UPMC.

Deliverable 4.1.3

Purpose

The goal was to implement the hypoglycemia treatment protocol (HTP) and continue to evaluate the effectiveness of the glycemic management protocols that were already implemented at WHMC. It was hypothesized that implementation of glycemic diabetes management protocols would lead to improved glycemic control and outcomes at WHMC.

Hypotheses

Hypothesis: Implementation of a glycemic diabetes management protocols in both WHMC will lead to improved glycemic control and outcomes.

Study Design

Standardized order sets that encompass critical aspects of glycemic management were introduced. Protocols for implementation were selected based on ongoing input and selection from WHMC staff. Protocols were presented to AF leadership at WHMC and approved. Implementation of the protocols was provided through a series of education sessions. Patient baseline data including demographic, reason for inpatient stay, and lab results was gathered. Severity of illness scores were originally proposed however these scores are not collected and recorded as part of WHMC admission process. Patient data was analyzed according to corresponding patient service codes. Daily plasma glucose and insulin requirement data was collected for each patient during their hospital stay. At discharge, the time to goal of blood glucose, change in glucose levels and hospital length of stay (LOS) were obtained.

Results

A total of 142 patients experienced a hypoglycemic event at WHMC from November 2009 through August 2009. The mean of age of patients was 66.35 (SD: 15.45) years and 80 (56.34%) were male. One hundred and seventeen (82.39%) patients were white, 18 (12.68%) were black/African American, and 7 (4.93%) were other races. Seven (4.93%) patients had type 1 diabetes, 111 (78.1%) had type 2 diabetes, and 24 (16.9%) did not have diabetes. The average HbA1C level was 7.5 (SD: 1.88) %; the average blood glucose was 168.94 (SD: 104.82) mg/dL at hospital admission. The LOS of hospitalization was 10.09 days (SD: 12.47) days. The average number of hypoglycemic events per patient was 1.83 (SD 1.9). Protocol use ranged from 0% (protocol not used in Hemetology/Oncology Unit) to 70.97% (Cardiology Unit). Total use across all units was 54.62%.

Achieving glycemic target ranges within a reasonable timeframe while avoiding adverse events has the potential to improve patient outcomes (lower risk of infection, improve healing, etc.) and decrease patient LOS. Albeit a shortened intervention time frame, the results of the implementation of the inpatient protocols in regards to glycemic management and LOS are encouraging. Hypoglycemic events were reduced when protocols were used while getting glucose to target range and LOS is comparable to others [44,,45]. Implementation of inpatient protocols in a military environment required us to address challenges specific to a military environment. Challenges encountered are described in a published abstract and reports [46].

A cost effectiveness analysis was also performed to examine the value of the hypoglycemia treatment protocols as applied at WHMC. The analysis found that the use of HTP on inpatient adults was cost saving in the eligible hospital admission sample. In alternative scenarios where additional capillary blood glucose (CBG) tests would be used in a HTP, the cost-effectiveness ratios related to HTP use were very strong and indicate that HTP is likely an efficient use of resources. Crude return on investment calculations indicate that HTP was associated with very large monetary returns in

terms of reduced LOS in the hospital, and, when implemented fully, was associated with meaningful returns in terms of reduced time to reach blood glucose targets.

While the results of the analysis were very encouraging, there are potential limitations that may affect the translation of these findings to broader audiences. First, this assessment was based upon the data submitted regarding the sample of patients with hypoglycemia episodes at WHMC between November 2009 and August 2010. These estimates of cost-effectiveness may change with data from different samples.

Second, it is important to point out that LOS may be influenced by several other factors than HTP. It would be incorrect to attribute all of the difference in LOS between HTP use and non-use to the enhanced health benefits of efficient blood glucose control. HTP, though, may have a significant role to play in LOS. The linear regression analysis found that HTP use was a significant and independent predictor for reduced LOS. The degree to which HTP may contribute to reduced LOS, however, is not clearly known at this time. On the other hand, the HTP use is likely to contribute very strongly to the differences noted in the time needed to reach target blood glucose values. This assessment noted worthwhile returns from the benefits gained with full HTP implementation following a hypoglycemia episode.

The strongest data on HTP use in this report likely lies in the role of HTP when applied on the general hospital floor in internal medicine or cardiology units. The implementation of HTP in intensive care unit (ICU) settings is a relatively recent initiative. While the results of this report indicate that HTP may be very efficient in ICU settings, one should use caution with these results. It is possible, for example, that the available data on the number of days spent in intensive care units was not accurate. It is also important to point out that only one-third of the hypoglycemia episodes occurring in intensive care units were treated with the HTP. Thus, it would be worthwhile to gain further insight into the economic value of HTP use in ICU settings.

Sensitivity analyses are a common feature of economic assessments. The results have considered two alternative scenarios for the implementation of HTP. These scenarios remained cost efficient in the analysis. Other alternative scenarios, however, may exist. For example, the values reported may differ if the cost values assigned to CBG tests and hospital days differ from those used here. The impact of a higher CBG cost, however, is not likely to affect the results reported meaningfully. The alternative scenario of 2 additional blood glucose tests, for example, is a crude way of examining what the results would look like if the cost of a CBG test were doubled.

This assessment provided a first look at the economic implications of HTP use at WHMC. Further assessments may be beneficial to consider a number of questions. These include the importance of the variability that might be associated with differing samples of patients, the value of HTP in patients with diabetes relative to patients without diabetes, and the value of HTP in intensive care

settings. This report, however, provided a fairly strong finding that HTP use, when implemented fully in general floor units, provides benefits to subjects and reduces their time to reach target blood glucose values. From a health care system perspective, HTP in this realm also provides significant returns in monetary value.

Conclusions

Strengths

- Developed multi-level education programs to facilitate implementation of the protocols
- Promoted consistency among all departments treating patients with hyper/hypoglycemia
- Inpatient Glycemic Management Team (IGMT) tracked glucose data and addressed hyper/hypo glycemia on a daily basis which assisted timely and appropriate application of protocols at WHMC
- IGMT performed diabetes focused patient interviews and documents in patient's chart all outpatient therapies relating to diabetes management. Helped guide inpatient care.
- IGMT evaluated protocol use and made recommendations to maintain, augment or decrease inpatient insulin therapy based on patients' clinical status

Weaknesses

- Delays with forms' approvals for protocols limited ability to fully implement and report on clinical outcomes during the period of performance
- Ongoing BRAC processes challenged processes and training
- HTP & Subcutaneous Insulin Protocol initiated at WHMC in November 2009, thus need to take into account that it took a minimum of 3 months to deploy the protocols and train the staff
- Paper-documentation for inpatient care made it cumbersome to collect data (i.e. wait for chart to be available, not all charts organized in same fashion and data points missing)
- Lengthy process to obtain necessary computer access cards limiting communication and data sharing between data collectors & IGMT at WHMC
- No access to real-time blood glucose meter results via Remote Automated Laboratory System (RALS). Thus, data evaluation was often a day behind & left a large gap of time before IGMT was able to intervene, e.g. some patients are missing RALS values.
- Frequent staff turn-over required frequent re-training on available protocols

Focus Area 4; Goal 1

Implement inpatient management protocols and continue to investigate and evaluate effectiveness of protocols at WHMC with support from UPMC.

Deliverable 4.1.7

Purpose

The goal was to determine the feasibility and benefits of establishing a Glycemic Management Team in a military inpatient facility.

Hypotheses

Hypothesis: Determine the feasibility and benefits of establishing glycemic management teams in military inpatient facilities

Study Design

In collaboration with the USAF medical staff, UPMC established a pilot program with an IGMT at WHMC. The IGMT included: a physician assistant, two advance practice nurses and two research assistants. The goals for the team were to implement a series of approved inpatient protocols, identify opportunities for improvement in glycemic management, provide training and make recommendations to the WHMC inpatient medical staff.

Results and Conclusions

It was determined that it is both feasible and beneficial to establish a Glycemic Management Team in a military inpatient facility given the following:

1) Ongoing staff education be provided for medical and nursing staff to reiterate the criticality of glycemic control in optimizing patient outcomes
2) Support an on-site medical champion to organize and lead a multi-disciplinary inpatient Advisory Committee
3) An Advisory Committee was established to develop strategies and timelines for the glycemic management team and the implementation of the protocols.
    a. UPMC recommended that there be representation of these departments on the advisory committee: Medical, nursing, pharmacy, nutrition services, laboratory, quality improvement, information systems, case management and administration.
    b. A thorough assessment of current processes at WHMC, quality of care, and barriers to practice changes be performed and addressed by the committee
    c. Based on recommendations of the Advisory Committee at the time, a Glycemic Management Team and on-site staff champion continued to implement and develop the following:
        - Standardized order sets
        - Protocols and algorithms

- Policies
- Educational Programs (Medical Staff and Nursing Teams)
- Metrics for Evaluations;
    - A system for tracking glucose control
    - Assess the quality of delivery of care
    - Quality improvement measurements

It was found that a Glycemic Management Team that consisted of 2 Advanced Practice Nurses, a Physician Assistant, and 2 Research Assistants was necessary to fully implement and evaluate 4 inpatient protocols at WHMC (230 beds) with the infrastructure at the time.

Reportable Outcomes

So Jung Lee prepared manuscripts to be submitted to medical journals (e.g. Lancet, Diabetes Care) in the spring of 2011. In addition, she gave the following presentation at the American Diabetes Association (ADA) annual meeting in 2010.

Lee SJ, Kim YM, Guerra N, Prince A, Bacha F, Arslanian S. Effects of exercise training without calorie restriction on total and abdominal fat, and *in vivo* insulin sensitivity in obese boys: A randomized controlled trial. Presented at the ADA Annual Meeting. Orlando, FL. 2010.

A manuscript was prepared based on this study to be submitted to the *Journal of Pediatrics*. In addition, a poster presentation was given at the National Initiative for Children's Healthcare Quality (NICHQ) Annual Forum in 2010.

Drnach M, Krall J. Development and implementation of Web-based educational tools to address pediatric obesity. NICHQ Annual Forum for Improving Children's Healthcare and Childhood Obesity Congress. Atlanta GA. 2010.

Piatt G, Seidel M, Powell R, Bednez J, Wolf D, Zgibor J. Community-Based Screening for Diabetes and CVD Risk in Rural Pennsylvania: The Rethinking Eating and ACTivity Study**.** CDC Division of Diabetes Translation Annual Conference. Minneapolis, MN, April 2011. Submitted October, 2010.

Bednez J, Powell R, Wolf D, Piatt G. Physical Activity Levels in Overweight Adults in Rural Pennsylvania: The Rethinking Eating and ACTivity Study. American College of Sports Medicine Annual Meeting. Denver, Colorado. May 2011. Submitted October, 2010.

Seidel M, Piatt G. The Association between Underreporting of Caloric Intake and Achieving Weight Loss following a Group Lifestyle Balance Program: Results of the Rethinking Eating and ACTivity Study (REACT). American Dietetic Association Food & Nutrition Conference & Expo. San Diego, CA. September 2011. Will be submitted January, 2011.

Appendix A: Acronyms Definitions

Acronym	Definition
ADA	American Diabetes Association
AF	Air Force
AFB	Air Force Base
AFMS	Air Force Medical Service
AHA	American Heart Association
BAMC	Brook Army Medical Center
BMI	Body Mass Index
BP	Blood Pressure
BPC	Big Picture Communications
CBG	capillary blood glucose
CCM	Chronic Care Model
CDE	Certified Diabetes Educators
CEA	Cost-Effectiveness Analysis
CHCS	Composite Health Care System
CHP	Children's Hospital of Pittsburgh of UPMC
CMU	Carnegie Mellon University
CPT	Current Procedural Terminology
CVD	Cardiovascular Disease
DCOE	Diabetes Center of Excellence
DOC	Diabetes Outreach Clinic
DoD	Department of Defense
DPP	Diabetes Prevention Program's
DPSC	Diabetes Prevention Support Center
DSME	Diabetes Self-Management Education
ERP	Education Recognition Program
ETDRS	Early Treatment Diabetic Retinopathy Study
GLB	Group Lifestyle Balance
HB4L	Healthy Behaviors for Life
HRQOL	Health Related Quality of Life
HTP	Hypoglycemia Treatment Protocol
ICD-9	International Statistical Classification of Diseases and Health Related Problems
ICU	Intensive Care Unit
IGMT	Inpatient Glycemic Management Team
LPN	Licensed Practical Nurses
LOS	Length of Stay

mDPP	Diabetes Prevention Program
MEPRS	Medical Expense and Performance Reporting System
MetS	Metabolic Syndrome
MNT	Medical Nutritional Therapy
NACHRI	National Association of Children's Hospitals and Related Institutions
NHANES	National Health and Nutrition Examination Survey
PARC	Physical Activity Resource Center
PARC-PH	Physical Activity Resource Center for Public Health
PCM	Primary Care Manager
PCP	Primary Care Physician
PCTRC	Pediatric Clinical and Translational Research Center
PedsQL	Pediatric Quality of Life Inventory
PHIT	Pittsburgh-Hershey Internet Translation
PRIDE	Pittsburgh Regional Initiative for Diabetes Education
QALY	Quality Adjusted Life Year
RALS	Remote Automated Laboratory System
RCT	Randomized Control Trial
REACT	The Rethinking Eating and Activity Study
RFP	Request for Proposal
SAMMC	San Antonio Military Medical Center
SAMPC	San Antonio Military Pediatric Center
SAOI	Self-Access to Online Information
SAS	Statistical analysis system
SNARC	Self-administered non-mydriatic retinal camera
T1D	Type 1 Diabetes
T2D	Type 2 Diabetes
UC	Usual Care
UPDI	University of Pittsburgh Diabetes Institute
US	United States
USAF	United States Air Force
VLM	Virtual Lifestyle Management
WHMC	Wilford Hall Medical Center
WMWC	Weight Management and Wellness Center

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